

**THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant(s): Christiana Soldani  
Appl. No.: 10/695,833  
Conf. No.: 7187  
Filed: October 30, 2003  
Title: CONFECTIONERY PRODUCT  
Art Unit: 1794  
Examiner: A. Corbin  
Docket No.: 112701-587

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPELLANTS' APPEAL BRIEF**

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on April 29, 2008. This Appeal is taken from the Final Rejection in the Office Action dated January 8, 2008.

**I. REAL PARTY IN INTEREST**

The real party in interest for the above-identified patent application on Appeal is Nestec S.A. by virtue of an Assignment dated February 4, 2004 and recorded at reel 014307, frame 0234 in the United States Patent and Trademark Office.

## **II. RELATED APPEALS AND INTERFERENCES**

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

### **III. STATUS OF CLAIMS**

Claims 1, 3, 5-6 and 8-17 are pending in the above-identified patent application. Claims 2, 4 and 7 were previously canceled and Claims 13-17 were previously withdrawn. Claims 1, 3, 5-6 and 8-12 stand rejected. Therefore, Claims 1, 3, 5-6 and 8-12 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

#### **IV. STATUS OF AMENDMENTS**

A Non-Final Office Action was mailed on September 4, 2007, in which the Examiner rejected Claims 1 and 3 as being indefinite and Claims 1, 3-6 and 8-12 as obvious in view of several references. Appellants filed a Response in reply to the Non-Final Office Action on December 4, 2007 addressing the deficiencies of the cited references and the merits of the indefiniteness rejections. A Final Office Action was mailed on January 8, 2008, wherein the Examiner withdrew the rejection of Claim 1 as indefinite, maintained the rejection of Claim 3 as indefinite and maintained the obviousness rejections. Copies of the Non-Final Office Action and the Final Office Action ("Office Action") are attached as Exhibits A and B, respectively, in the Evidence Appendix.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a method for the manufacture of a glassy amorphous solid as a confectionery material (page 3, lines 1-2), the glassy amorphous solid comprising at least one acidic component and at least one sugar alcohol which is not a monosaccharide sugar alcohol (page 3, lines 2-4), the method comprising the steps of: (i) forming a liquid starting material comprising water, the at least one acidic component, and the at least one sugar alcohol which is not a monosaccharide sugar alcohol (page 3, lines 5-6); (ii) evaporating water from the liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material (page 3, lines 7-10), wherein the evaporating is carried out at a temperature that does not exceed 145°C (page 4, lines 17-18); and (iii) cooling the intermediate material to form a glassy amorphous solid that has improved transparency compared to a glassy amorphous solid in which the acidic component has been added after a cooking step (page 3, lines 11-12; page 4, lines 9-13; page 5, line 28-page 6, line 11), wherein the water content of the intermediate material is reduced to below 3% (page 5, line 33-page 6, line 2).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the reference numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the reference numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

**VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. Claim 3 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.
2. Claims 1, 3, 5-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being as unpatentable over EP 1 151 673 to Rivier ("*Rivier*"). A copy of *Rivier* is attached herewith as Appendix C.
3. Claims 1, 3, 5-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being as unpatentable over U.S. Patent No. 4,154,867 to Aldrich et al. ("*Aldrich*") or U.S. Patent No. 3,738,845 to Liebrand ("*Liebrand*") in view of *Rivier*. Copies of *Aldrich* and *Liebrand* are attached herewith as Appendices D and E, respectively.

## VII. ARGUMENT

### A. LEGAL STANDARDS

#### Definiteness under 35 U.S.C. § 112, second paragraph

The standard for determining whether the definiteness requirement is met under 35 U.S.C. § 112, ¶ 2 is “whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification.” *Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 1 U.S.P.Q. 2d 1081-1088 (Fed. Cir. 1986). “If the claims, read in light of the Specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the Courts can demand no more.” *North American Vaccine Inc. v. American Cyanamid Co.*, 28 U.S.P.Q. 2d 1333, 1339 (Fed. Cir. 1993). In this regard, “[p]atent law allows the inventor to be his own lexicographer ... [T]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification. *United States v. Teletronics, Inc.*, 8 U.S.P.Q. 2d 1217, 1220 (Fed. Cir. 1988). By statute, 35 U.S.C. 112, Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention.” *In re Pilkington*, 162 U.S.P.Q. 145, 148 (C.C.P.A. 1996).

#### Obviousness under 35 U.S.C. § 103

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

*In re Mayne*, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This



burden may only be overcome “by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings.” *In re Fine*, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). “If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent.” *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Patent Office must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court has emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

## B. THE CLAIMED INVENTION

Independent Claim 1 recites, in part, a method for the manufacture of a glassy amorphous solid as a confectionery material. The glassy amorphous solid includes at least one acidic component and at least one sugar alcohol which is not a monosaccharide sugar alcohol. The method includes the steps of forming a liquid starting material comprising water, the at least one acidic component, and the at least one sugar alcohol which is not a monosaccharide sugar alcohol. The method also includes the step of evaporating water from the liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145°C. Further, the method also includes the step of cooling the

intermediate material to form a glassy amorphous solid that has improved transparency compared to a glassy amorphous solid in which the acidic component has been added after a cooking step, wherein the water content of the intermediate material is reduced to below 3%.

C. CLAIM 3 IS SUFFICIENTLY DEFINITE TO SATISFY THE REQUIREMENTS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The standard for determining whether the definitiveness requirement is met under 35 U.S.C. §112, second paragraph, is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. With respect to the presently claimed subject matter, Appellants respectfully disagree with the Examiner's assertion that "[t]here is no antecedent basis in claim 1 for 'the cooking step'" of Claim 3 "since no positive cooking step is recited in claim 1." See, Office Action, page 2, lines 10-11. Instead, Appellants respectfully submit that the skilled artisan would understand the metes and bounds of the method for the manufacture of a glassy amorphous solid as a confectionery material.

Claim 3 is directed, in part, to the method of Claim 1 for the manufacture of a glassy amorphous solid as a confectionery material, the glassy amorphous solid including at least one acidic component and at least one sugar alcohol which is not a monosaccharide sugar alcohol. The subject matter of Claim 3 further narrows the method of Claim 1 by adding the method step of applying a vacuum to an evaporator during the cooking step to assist in removing water to reach a desired final water content of the intermediate material.

In response to the Non-Final Office Action dated September 4, 2007, Appellants amended independent Claim 1 to recite, in part, cooling the intermediate material to form a glassy amorphous solid that has improved transparency compared to a glassy amorphous solid in which the acidic component has been added after a cooking step. The amendment is supported in the specification at, for example, page 5, line 28-page 6, line 11. The amendment further defined the scope of the claims to highlight the difference between the prior art, wherein acid components are conventionally added towards the end of or after heat treatment or cooking, and the presently claimed subject matter, wherein the acid components may be added at the start of the process for the manufacture of a hard candy provided that conditions are used in the process under which the acid does not hydrolyze the sugar alcohol. Since Claim 1 recites, in part, "a cooking step," and Claim 3, which is dependent from Claim 1, recites, in part, "the cooking

step,” Appellants respectfully submit that there is proper antecedent basis for “the cooking step” in Claim 3.

As such, Appellants respectfully submit that, because the skilled artisan would understand the metes and bounds of the method for the manufacture of a glassy amorphous solid as a confectionery material, and because there exists proper antecedent basis for “the cooking step,” Claim 3 fully complies with 35 U.S.C. §112, second paragraph, and is in condition for allowance.

Accordingly, Appellants respectfully request that the rejection of Claim 3 under 35 U.S.C. §112, second paragraph be withdrawn.

D. THE REJECTION OF CLAIMS 1, 3, 5-6 AND 8-12 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully submit that the obviousness rejection of Claims 1, 3, 5-6 and 8-12 should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness. In the Office Action, the Examiner alleged that the claimed subject matter is rendered obvious by *Rivier*. However, the Examiner fails to establish a *prima facie* case of obviousness in each rejection because even if modification of *Rivier* is proper, *Rivier* fails to teach or suggest every element of the presently claimed subject matter. Moreover, there exists no reason why the skilled artisan would have modified *Rivier* to arrive at the presently claimed subject matter.

Independent Claim 1 is directed, in part, to a method comprising: (i) forming a liquid starting material comprising water, the at least one acidic component, and the at least one sugar alcohol which is not a monosaccharide sugar alcohol; (ii) evaporating water from the liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145°C; and (iii) cooling the intermediate material to form a glassy amorphous solid that has improved transparency compared to a glassy amorphous solid in which the acidic component has been added after a cooking step, wherein the water content of the intermediate material is reduced to below 3%.

As taught by Appellants' specification, hard candy is generally made by a process in which a mixture of the sugar or sugar alcohol and water is heated, generally under vacuum, at a temperature of about 130-150°C. The resulting mixture can be worked and formed into confectionery products as desired and, upon cooling, forms a glassy amorphous solid with a water content of less than 3%. Hard candy generally contains other ingredients, some of which can be acidic. As described in the specification, when significant hydrolysis of the sugar alcohol occurs, the resulting candy product is a sticky and hygroscopic product. Significant hydrolysis of the sugar alcohol may also result in the crystallization of the product. In turn, the sticky, hygroscopic nature of the candy and/or the crystallization of the product results in a tendency of the hard candy to be opaque. See, specification, page 1, line 20-page 2, line 2. This is not always a desirable property of a hard candy, and it may often be desirable for aesthetic reasons for a hard candy to be as transparent as possible.

Sugar alcohols which are not monosaccharide sugar alcohols show some susceptibility to acid hydrolysis. As such, acid components are conventionally added towards the end of or after heat treatment or cooking. However, hydrolysis of the sugar alcohol can occur, which in turn, results in a sticky, hygroscopic product and/or crystallization of the candy. In addition, by the time the acid component is added, the water content of the mixture has been reduced through evaporation, generally to around 2% or less. The acids are conventionally added as powder rather than pre-dissolved in water to avoid introducing additional water which would remain in the final composition and possibly have detrimental effects on the quality of the final product. This has the consequence that dissolution of the acid may be difficult or incomplete. As a result of these factors, there is a tendency of the hard candy to be a opaque.

One example of a commercially available sugar alcohol commonly used as a sugar substitute is Isomalt, which is made by enzymatic rearrangement of sucrose followed by hydrogenation. Isomalt is a mixture of the isomers 1-O- $\alpha$ -D-glucopyranosyl-D-mannitol dehydrate and 6-O- $\alpha$ -D-glucopyranosyl-D-sorbitol. In the processing of Isomalt into hard candy, flavor, color and citric acid are added at the cooling stage of the process after cooking is complete.

In accordance with the present disclosure, it has been surprisingly found that acidic component(s) which have conventionally been observed to hydrolyze the sugar alcohol can be added at the start of the process for the manufacture of a hard candy provided that conditions are

used in the process under which the acid does not hydrolyze the sugar alcohol. Generally, this involves the use of a vacuum evaporator to reach the desired final moisture content at a temperature which is low enough to avoid hydrolysis of the sugar alcohol. As a result, the problems referred to above are alleviated, and the resulting hard candy shows improved transparency.

Specifically, the specification compares two hard candy products, one made by a process in accordance with the presently claimed subject matter wherein the acidic component(s) are added before a cooking step, and the other made by a process in which the acidic component(s) are added after a cooking step. As shown by Table 1 and Figure 3, the hard candy products made by a process in accordance with the presently claimed subject matter clearly result in "improved" transparency over the hard candy product made a process in which the acidic component(s) are added after a cooking step.

When the acidic component is added at the beginning of the process, before evaporation (*i.e.*, before cooking), according to the present disclosure, transmission for a hard candy has been found to be consistently greater than with a comparable product made by a method using addition of acidic ingredients during cooling (*i.e.*, after cooking). See, specification, Example 1 and Table 1. Appellants' Comparative Example 2 shows that, when the acid is added during cooling after cooking and vacuuming, the candy product is more opaque than that of Example 1 where the acidic component is added before cooking.

Moreover, the evaporation is carried out at a temperature not exceeding 148°C, more preferably, not exceeding 145°C. Thus, the present disclosure relates to a method for preparing a hard candy, which includes at least one acidic component and which shows improved transparency. Such a hard candy is made by forming a liquid starting material comprising at least one sugar alcohol which is not a monosaccharide sugar alcohol, water and the acidic component; heating under conditions not above 148°C, preferably not above 145°C, at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and remove at least part of the water; and cooling to form the hard candy with a final water content of an intermediate material below 3%.

Thus, Appellants respectfully submit that the "improved" transparency, as used by Appellants in the specification, correlates to the higher transmission values of a hard candy product produced where in the acidic component(s) are added before cooking, as opposed to

after cooking. Appellants respectfully submit that the specification clearly illustrates that the transmission values of the product made in Example 1 are clearly higher, or “improved,” when compared to the product made in Example 2. In contrast, Appellants respectfully submit that *Rivier* is deficient with respect to the present claims.

1. As set forth in the Affidavit that the Examiner improperly failed to consider, Rivier fails to disclose or suggest all of the elements of the present claims

Even if modification of *Rivier* is proper, Appellants submit that *Rivier* fails to disclose or suggest every limitation of Claim 1 and, therefore, dependent Claims 3-6 and 8-12 that depend therefrom. For example, *Rivier* fails to disclose or suggest forming a liquid starting material comprising water and at least one acidic component, and evaporating water from the liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol as required, in part, by Claim 1.

As support for this position, Appellants have attached hereto as Exhibit F, the *Affidavit* previously filed in related U.S. Application No. 11/314,042. Appellants note the Examiner failed to consider the *Affidavit*, stating that it is “not . . . relevant in the instant application since it is an affidavit pertaining to the disclosure of SN 11/314, 042.” See, Office Action, page 3, lines 6-8. The Examiner’s failure to consider the *Affidavit* in accordance with U.S. Patent Office procedures is sufficient basis alone for this Board to reverse the rejections.

The Manual of Patent Examining Procedure (MPEP) states that “[w]here it is desired to rely on an earlier filed affidavit or declaration, the applicant should make such remarks of record in the 37 CFR 1.53(b) application and include a copy of the original affidavit or declaration filed in the prior nonprovisional application.” See, MPEP 201.06(c)(IX). Appellants respectfully submit that the *Affidavit* and related remarks were made of record in the Response dated April 8, 2008. Because the *Affidavit* and related remarks were made of record in the Response dated April 8, 2008, Appellants respectfully submit that the Examiner is required to consider the *Affidavit* previously filed in the instant case.

As demonstrated in the *Affidavit* attached hereto as Exhibit F, *Rivier* (referred to in the *Affidavit* as “*Rivier II*”) *Rivier* teaches a conventional process for producing confectionery products wherein acidic components are added after cooking. See, *Rivier*, [0059], [0060], Example 1, and *Affidavit*. Appellants have shown in comparative Example 2 of the specification

that when the acid is added during cooling, after cooking and vacuuming, the final candy product is more opaque than that made according to the claimed method (Example 1), which involves the acidic component added before cooking the liquid starting material. Because *Rivier* discloses a method of making a hard candy wherein acidic components are added after cooking, *Rivier* cannot disclose a method wherein a liquid starting material comprising water, at least one acidic component and at least one sugar alcohol is formed as required, in part, by the present claims.

Moreover, Appellants respectfully disagree with the Examiner's assertion that "[Appellants] contention [that *Rivier* discloses adding the acidic component after cooking teaches away from the present invention wherein the acid is added prior to cooking] is without merit as *Rivier* clearly discloses the presence of an acid before cooking of the liquid composition therein at 130 °C (col. 13, lines 52-55 and col. 14, lines 28-33)." See, Office Action, page 3, lines 9-13. In contrast, however, Appellants respectfully submit that *Rivier* does not, in fact, "clearly disclose[] the presence of an acid before cooking of the liquid composition therein at 130 °C."

Instead, column 13, lines 52-55 of *Rivier* clearly discloses that "[r]elevant additives such as . . . acids or sweeteners can be added in conventional amounts to the composition of the casing." Further, column 14, lines 28-33 of *Rivier* disclose that the casings of *Rivier* can be "obtained by dehydration of slurries made of aqueous mixtures of saccharides and/or polyhydric alcohols which is boiled in suitable proportions in a cooker at a temperature of 130-150 °C." As such, Appellants respectfully submit that, even though *Rivier* discloses that acids may be added to the composition of the casing, the portions of *Rivier* cited by the Examiner fail to indicate, at any place therein, that *Rivier* discloses the presence of an acid before cooking of the liquid composition, as suggested by the Examiner. In fact, in at least Example 1 of *Rivier*, it is clearly disclosed that the acid of the casing is added after cooking. See, *Rivier*, Example 1.

Appellants also remain at odds with the Examiner's assertion that "*Rivier* discloses preparing a confectionery product from a starting liquid composition including water, citric acid and sorbitol, maltitol, isomalt or a mixture of these polyols." See, Office Action dated September 4, 2007, page 2, lines 20-22 (emphasis added). Instead, *Rivier* cannot teach a starting liquid composition having citric acid because *Rivier* teaches a conventional process for producing confectionery products wherein acidic components are added after cooking. See, *Rivier*, [0059], [0060], Example 1 and *Affidavit*. Indeed, Appellants have described comparative

examples that show the differences in transparency of the final candy product made by processes involving adding acid to the liquid mixture before a cooking step (claimed process) versus adding acid to the cooked composition during cooling and vacuuming of the product (*Rivier*). Consequently, Appellants' claimed process is distinguishable from *Rivier*, and the finished product of *Rivier* would not have improved transparency in accordance with the present disclosure. For at least the reasons discussed above, Appellants respectfully submit that Claims 1, 3, 5-6 and 8-12 are novel, nonobvious and distinguishable from *Rivier*.

2. One having ordinary skill in the art would have no reason to modify *Rivier* to arrive at the present claims

Appellants respectfully submit that the skilled artisan would have no reason to modify *Rivier* to arrive at the presently claimed subject matter because *Rivier* teaches away from the present disclosure. As discussed above, Appellants have attached hereto as Exhibit F, the *Affidavit* previously filed in related U.S. Application No. 11/314,042. As demonstrated in the *Affidavit*, *Rivier* (referred to in the *Affidavit* as "*Rivier II*") teaches a conventional process for producing confectionery products wherein acidic components are added after cooking. Specifically, *Rivier* teaches that a mixture of 80 Kg of isomalt, 10 Kg of maltitol syrup and 10 Kg of water is cooked under 60% vacuum until reaching a cooking temperature of 155°C. Subsequently, the resulting cooked mass is flavoured, coloured, and acidified and cooled down at 70°C. See, *Rivier*, Example 1.

As further demonstrated in the *Affidavit*, addition of acidic component(s) post-cooking will not result in a glassy amorphous solid having an improved transparency as evidenced by the transmission levels required by a product produced by a manufacturing process of the present disclosure. Similarly, a method wherein the acidic components are added post-cooking is in direct contrast to the method of the present disclosure in which the acidic components are added before cooking. Because *Rivier* adds the acidic components of the hard candy after cooking, *Rivier* teaches away from the present claimed subject matter including a method of making a hardy candy product in which the acidic components are added prior to a cooking stage. As such, Appellants respectfully submit that the skilled artisan would have no reason to modify *Rivier* to arrive at the present claims.



Accordingly, Appellants respectfully request that the rejection of Claims 1, 3, 5-6 and 8-12 under 35 U.S.C. §103 be withdrawn.

E. THE REJECTION OF CLAIMS 1, 3, 5-6 AND 8-12 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS

Appellants respectfully submit that, even if combinable, the cited references are deficient with respect to the present claims because the cited references, either alone or in combination, fail to disclose each and every limitation of the present claims. For example, *Aldrich* is deficient with respect to independent Claim 1 for several reasons. *Aldrich* fails to disclose or suggest evaporating water from a liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145 °C. In fact, in all of the Examples, *Aldrich* teaches dissolving acidic components in a liquid using temperatures of 330-335 °C (about 165 °C to 167 °C). Further, *Aldrich* teaches away from using other acids such as citric acid, which are suitable in the present disclosure. *Aldrich* also discloses the use of sorbitol (e.g., a monosaccharide sugar alcohol) as the preferred sugar alcohol whereas, in the present disclosure, the sugar alcohol used is specifically not a monosaccharide sugar alcohol. Moreover, the acid used in *Aldrich* is not added at the start of the process (see, Example 1 where malic acid is added later in the processing) as is the case with the present disclosure. Also, *Aldrich* is wholly silent on the water content of the final product.

In addition to the above-mentioned differences, the problem sought to be solved by *Aldrich* and the present disclosure are completely different. The aim of *Aldrich* is to improve the flavor of a candy, whereas an object of the present disclosure is to obtain a product having improved transparency. *Aldrich* states at column 1, lines 40-44, “[s]urprisingly, in accordance with the present disclosure, the above flavor problems associated with the use of citric acid in combination with hydrogenated starch hydrolysates and sorbitol has been resolved by replacing the citric acid with malic acid.”

Similarly, *Liebrand* is also deficient with respect to the present claims for several reasons. *Liebrand* fails to disclose or suggest evaporating water from a liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145 °C because *Liebrand* teaches evaporating water at a temperature of “at least 300 °F” and up to 350 °F (about 149 °C to about 177 °C). Further, *Liebrand* discloses the use of sorbitol (*e.g.*, a monosaccharide sugar alcohol) as the preferred (and only) sugar alcohol whereas, in the present disclosure, the sugar alcohol used is specifically not a monosaccharide sugar alcohol.

Further, *Rivier* is deficient with respect to the presently claimed subject matter for at least the reasons set forth above. *Rivier* is also deficient with respect to the present claims because *Rivier* fails to disclose or suggest evaporating water from a liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145 °C as required, in part, by the presently claimed subject matter. Instead, *Rivier* teaches cooking its hard candy product at a temperature of 155 °C, which is clearly higher than the temperature of 145 °C allowed by process of the present disclosure. Moreover, because *Rivier* fails to disclose or suggest a liquid starting material having an acidic component added prior to cooking, *Rivier* cannot disclose or suggest evaporating water from a liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145 °C.

The Examiner alleges that “*Rivier* renders it obvious to cook at such a temperature in the process of either *Aldrich* et al or *Liebrand* . . . [and that] *Rivier* also renders it obvious to use isomalt or maltitol in place of the sorbitol in *Aldrich* et al.” See, Office Action, page 3, lines 13-19. However, because *Aldrich*, *Liebrand* and *Rivier* are all deficient with respect to the present claims, Appellants respectfully disagree with the Examiner’s assertion that it would have been obvious to combine the cited references to arrive at the present claims. In contrast, Appellants

respectfully submit that the skilled artisan seeking to improve the transparency of a hard candy would have no reason to combine the cited references to arrive at the present claims because they fail to disclose or suggest every element of the present claims and actually teach away from the present claims.

For at least the reasons discussed above, Appellants respectfully submit that Claims 1, 3, 5-6 and 8-12 are novel, nonobvious and distinguishable from the cited references.

### VIII. CONCLUSION

Appellants respectfully submit that Claim 3 meets the requirements of 35 U.S.C. §112, second paragraph. Moreover, Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) with respect to the rejections of Claims 1, 3, 5-6 and 8-12. Accordingly, Appellants respectfully submit that the indefiniteness and obviousness rejections are erroneous in law and in fact and should, therefore, be reversed by this Board.

The Director is authorized to charge \$500 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-587 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

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Dated: June 4, 2008

**CLAIMS APPENDIX**  
**PENDING CLAIMS ON APPEAL OF**  
**U.S. PATENT APPLICATION SERIAL NO. 10/695,833**

1. A method for the manufacture of a glassy amorphous solid as a confectionery material, the glassy amorphous solid comprising at least one acidic component and at least one sugar alcohol which is not a monosaccharide sugar alcohol, the method comprising the steps of:

(i) forming a liquid starting material comprising water, the at least one acidic component, and the at least one sugar alcohol which is not a monosaccharide sugar alcohol;

(ii) evaporating water from the liquid starting material under conditions at which the acidic component does not cause significant hydrolysis of the sugar alcohol to dissolve the acidic component in the liquid and to remove at least part of the water to form an intermediate material, wherein the evaporating is carried out at a temperature that does not exceed 145°C; and

(iii) cooling the intermediate material to form a glassy amorphous solid that has improved transparency compared to a glassy amorphous solid in which the acidic component has been added after a cooking step, wherein the water content of the intermediate material is reduced to below 3%.

3. The method of claim 1 which further comprises applying a vacuum to an evaporator during the cooking step to assist in removing water to reach a desired final water content of the intermediate material.

5. The method of claim 3 which further comprises conducting the evaporating in multiple stages with a reduced pressure being applied in some or all of the stages.

6. The method of claim 3 wherein the liquid starting material is fed to an evaporator at a temperature of about 115-125°C where water is removed without application of a vacuum to form a partially dehydrated mass, which is then fed to the vacuum evaporator under vacuum at a temperature of 135-140°C where further water is removed to reach the final water content of the intermediate material.

8. The method of claim 1 wherein the sugar alcohol is selected from isomalt, maltitol, lactitol, polydextrose and combinations thereof.

9. The method of claim 1 wherein the sugar alcohol is isomalt or a mixture of isomalt with up to 20% of maltitol syrup.

10. The method of claim 1 wherein the acid is one or more of citric, malic, lactic, tartaric and fumaric acids.

11. The method of claim 1 wherein the acid is present in an amount of up to 2% by weight.

12. The method of claim 10 wherein the acid is present in an amount of from 0.3 to 1% by weight.

**EVIDENCE APPENDIX**

EXHIBIT A: Non-Final Office Action dated September 4, 2007

EXHIBIT B: Final Office Action dated January 8, 2008

EXHIBIT C: EP 1151673 to Rivier ("*Rivier*")

EXHIBIT D: U.S. Patent No. 4,154,867 to Aldrich et al. ("*Aldrich*")

EXHIBIT E: U.S. Patent No. 3,738,845 to Liebrand ("*Liebrand*")

EXHIBIT F: *Affidavit* of Christiana Soldani under 37 C.F.R. §1.132

# **EXHIBIT A**





## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/695,833      | 10/30/2003  | Cristiana Soldani    | 112701-587          | 7187             |

29157 7590 09/04/2007  
BELL, BOYD & LLOYD LLP  
P.O. Box 1135  
CHICAGO, IL 60690

EXAMINER  
CORBIN, ARTHUR L

ART UNIT PAPER NUMBER  
1761

NOTIFICATION DATE DELIVERY MODE  
09/04/2007 ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding. *Due: 12-4-07: Nov 1, 2007*

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

RECEIVED  
BELL, BOYD & LLOYD  
INTELLECTUAL PROPERTY DOCKET  
SEP 05 2007  
ATTY: *hmb-nyp*  
DOCKET #: *112701*

*387*

# Office Action Summary

Application No.

10/695,833

Applicant(s)

SOLDANI, CRISTIANA

Examiner

Arthur L. Corbin

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

1. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in failing to recite what is intended by "significant" hydrolysis (step ii) and by "improved" transparency (step iii). Claim 1 is further indefinite in not reciting to what "the water content" (step iii) refers. Also, there is no antecedent basis in claim 1 for "cooking" (step iii). Claim 3 is indefinite in not reciting when and to what the vacuum is applied. Corrections are required without new matter.

2. Claim 6 is objected to because of the following informalities: In claim 6, line 3, a comma should be added after "mass", and line 4, "down" should be cancelled. Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivier (EP 1 151 673 A2, cols. 13, 14 and 17-19). Rivier discloses preparing a confectionery product from a starting liquid composition including water, citric acid and sorbitol, maltitol, isomalt or a mixture of these polyols. The composition is cooked at 130 C under vacuum conditions and then cooled to form a plastic mass which is subsequently filled with a center filling. It would have been obvious that the

cooking in Rivier evaporates water from the composition without causing significant hydrolysis of the polyol since said cooking is performed at a temperature as claimed by applicant. Further, finding the optimum water content and acid content of the confectionery product (claims 1, 11, 12) would require nothing more than routine experimentation by one reasonably skilled in this art. The use of a vacuum evaporator to apply a vacuum (claim 4) and multi-stage cooking (claims 5 and 6) are conventional in this art and in the absence of unexpected results are entitled to no patentable weight.

5. Claims 1, 3-6 and 8-12 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Aldrich et al (4,154,867, col. 2) or Liebrand (3,738,845, cols. 1-2) in view of Rivier. Both primary references disclose preparing sugarless confections by cooking a composition including water, sorbitol and 0.2 % or 0.5 % citric or malic acid. The cooked composition is then cooled to form the final product. It would have been obvious to substitute isomalt or maltitol for the sorbitol in either primary reference and to perform the cooking therein under vacuum and at applicant's claimed temperature since it is well known to use sorbitol, isomalt and maltitol as alternative sweeteners in preparing confectionery products and to cook the confectionery composition under vacuum at a temperature of 130C, as evidenced by Rivier. Further, see the last three sentences in paragraph no. 4 above.

6. Claims 13-17 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Election was made **without** traverse in the reply filed on November 21 , 2005.

7. Applicant's arguments with respect to claims 1, 3-6 and 8-12 submitted November 3, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arthur L. Corbin whose telephone number is (571) 272-1399. The examiner can normally be reached on Monday-Friday from 10:30 AM to 8:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith D. Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/695,833  
Art Unit: 1761

Page 5

A handwritten signature in black ink, appearing to read 'Arthur L. Corbin', with a long horizontal stroke extending to the right.

Arthur L. Corbin  
Primary Examiner  
Art Unit 1761

8-28-07

**Search Notes**

Application/Control No.

10/695,833

Examiner

Arthur L. Corbin

Applicant(s)/Patent under  
Reexamination

SOLDANI, CRISTIANA

Art Unit

1761

082807

**SEARCHED**

| Class | Subclass | Date      | Examiner |
|-------|----------|-----------|----------|
| 426   | 103,660  |           |          |
|       | 492,524  |           |          |
| Above | Updated  | 8/28/2007 | ALC      |
|       |          |           |          |
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**INTERFERENCE SEARCHED**

| Class | Subclass | Date | Examiner |
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**SEARCH NOTES  
(INCLUDING SEARCH STRATEGY)**

|  | DATE | EXMR |
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# **EXHIBIT B**





## UNITED STATES PATENT AND TRADEMARK OFFICE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/695,833      | 10/30/2003  | Cristiana Soldani    | 112701-587          | 7187             |

29157 7590 01/08/2008  
BELL, BOYD & LLOYD LLP  
P.O. Box 1135  
CHICAGO, IL 60690

EXAMINER

CORBIN, ARTHUR L

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

01/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding. *Due: 4-8-08 - FINAL RES. ON*

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

**RECEIVED**  
BELL, BOYD & LLOYD  
INTELLECTUAL PROPERTY DOCKET

JAN 08 2008

ATTY: *fmb-PAC*DOCKET #: *112701-**587*

# Office Action Summary

Application No.

10/695,833

Applicant(s)

SOLDANI, CRISTIANA

Examiner

Arthur L. Corbin

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11-20-07, 12-04-07, 12-13-07.  
 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 8-17 is/are pending in the application.  
 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1,3,5,6 and 8-12 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 112007.121307

- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) ☐ Notice of Informal Patent Application  
 6) ☐ Other: \_\_\_\_\_

1. Claims 13-17 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 21, 2005.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in claim 1 for "the cooking step" (claim 3, line 2) since no positive cooking step is recited in claim 1. Without such a positive cooking step there can be no evaporator. Correction is required without new matter.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, 5, 6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rivier (EP 1 151 673, cols. 13, 14, 17-19) as set forth in paragraph no. 4, Paper No. 20070829.

6. Claims 1, 3, 5, 6 and 8-12 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Aldrich et al (4,154,867, col. 2) or Liebrand (3,738,845, cols. 1-2) in view of Rivier as set forth in paragraph no. 5, Paper No. 20070829.

7. Applicant's arguments filed December 4, 2007 have been fully considered but they are not persuasive. Initially, it should be noted that the "Affidavit" discussed by applicant on page 10 of the remarks has not been attached as Exhibit A. Further, even if such affidavit was attached, it would not be relevant in the instant application since it is an affidavit pertaining to the invention in SN 11/314,042.

Applicant's primary concern with regard to Rivier is that it discloses adding the acidic component after cooking thereby teaching away from applicant's step of adding the acid prior to cooking. Applicant's contention is without merit as Rivier clearly discloses the presence of an acid before cooking of the liquid composition therein at 130 C (col. 13, lines 52-55 and col. 14, lines 28-33). Although Aldrich et al and Liebrand fail to disclose applicant's cooking temperature of 145 C or less in order to prevent significant hydrolysis of the sugar alcohol by the acid, as applicant argues, Rivier renders it obvious to cook at such a temperature in the process of either Aldrich et al or Liebrand, as set forth in paragraph no. 5, Paper No. 20070829. Further, Rivier also renders it obvious to use isomalt or maltitol in place of the sorbitol in Aldrich et al as set forth in said paragraph no. 5.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

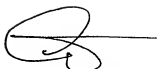
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arthur L. Corbin whose telephone number is (571) 272-1399. The examiner can normally be reached on Monday-Friday from 10:30 AM to 8:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton I. Cano, can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number:  
10/695,833  
Art Unit: 1794

Page 5

A handwritten signature in black ink, consisting of a large, stylized loop followed by a horizontal line extending to the right.

Arthur L. Corbin  
Primary Examiner  
Art Unit 1794

12-31-07

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                  |
|------------------------|------------------|
| Application Number     | 10695833         |
| Filing Date            | 2003-10-30       |
| First Named Inventor   | C. Soldani       |
| Art Unit               | 1761             |
| Examiner Name          | Arthur L. Corbin |
| Attorney Docket Number | 112701-587       |

**U.S. PATENTS**

| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|---------------|------------------------|------------|---|--|
| AC                | 1       | 3738845       |                        | 1973-06-12 | J.T. Liebrand                                   |  |
|                   | 2       | 4154867       |                        | 1979-05-15 | Aldrich et al.                                  |  |
|                   | 3       | 4971798       |                        | 1990-11-20 | Cola et al.                                     |  |
|                   | 4       | 5167981       |                        | 1992-12-01 | Mergelsberg et al.                              |  |
|                   | 5       | 5314708       |                        | 1994-05-24 | Gonze et al.                                    |  |
|                   | 6       | 5629042       |                        | 1997-05-13 | Serpelloni et al.                               |  |
| AC                | 7       | 6455096       |                        | 2002-09-24 | Katagiri et al.                                 |  |

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S. PATENT APPLICATION PUBLICATIONS**



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

|                        |                  |
|------------------------|------------------|
| Application Number     | 10695833         |
| Filing Date            | 2003-10-30       |
| First Named Inventor   | C. Soldani       |
| Art Unit               | 1761             |
| Examiner Name          | Arthur L. Corbin |
| Attorney Docket Number | 112701-587       |

| Examiner Initial* | Cite No | Publication Number | Kind Code <sup>1</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|---|--|
|                   | 1       |                    |                        |                  |   |  |


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**FOREIGN PATENT DOCUMENTS**

| Examiner Initial*  | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> j | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
|--|---------|--------------------------------------|-----------------------------|------------------------|------------------|---|--|--------------------------|
|  | 1       | EP 1151672                           | EP                          |                        | 2001-11-07       |   |  | <input type="checkbox"/> |
|  | 2       | EP 1151673                           | EP                          |                        | 2001-11-07       |   |  | <input type="checkbox"/> |

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials*   | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>5</sup>           |
|--|---------|--|--------------------------|
|  | 1       | Fritzsche, B. "ISOMALT IN HARD CANDY APPLICATIONS," Vol. 75. No. 11, pp. 65-73 (1995)  | <input type="checkbox"/> |

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

|                    |   |                 |          |
|--------------------|---|-----------------|----------|
| Examiner Signature |  | Date Considered | 12-31-07 |
|--------------------|---|-----------------|----------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Not for submission under 37 CFR 1.99) | Application Number   | 10695833          |
|  | Filing Date          | 2003-10-30        |
|  | First Named Inventor | Christina Soldani |
|  | Art Unit             | 1761              |
|  | Examiner Name        | Arthur L. Corbin  |
| Attorney Docket Number   |                      | 112701-587        |

| U.S. PATENTS      |         |               |                        |            |   |  |
|-------------------|---------|---------------|------------------------|------------|---|--|
| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
| pn                | 1       | 4452825       |                        | 1984-06-05 | Klaciak   |  |

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
| U.S. PATENT APPLICATION PUBLICATIONS |         |                    |                        |                  |   |  |
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| Examiner Initial*        | Cite No | Foreign Document Number <sup>3</sup> | Country Code <sup>2</sup> | Kind Code <sup>4</sup> | Publication Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear | T <sup>5</sup>           |
| pn                       | 1       | DE 19642363                          | DE                        |                        | 1998-04-16       |   |  | <input type="checkbox"/> |
| pn                       | 2       | GB 2 125 675                         | GB                        |                        | 1984-03-14       |   |  | <input type="checkbox"/> |
| pn                       | 3       | EP 0 533 334                         | EP                        |                        | 1993-03-24       |   |  | <input type="checkbox"/> |

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\*EXAMINER: Initial If reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**Search Notes**

Application/Control No.

10/695,833

Examiner

Arthur L. Corbin

Applicant(s)/Patent under  
Reexamination

SOLDANI, CRISTIANA

Art Unit

1794

123107

**SEARCHED**

| Class | Subclass | Date       | Examiner |
|-------|----------|------------|----------|
| 426   | 103,660  |            |          |
|       | 492,524  |            |          |
| Above | Updated  | 12/31/2007 | ALC      |
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**INTERFERENCE SEARCHED**

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**SEARCH NOTES  
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# EXHIBIT C

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Europäisches Patentamt  
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(11)

**EP 1 151 673 A2**

(12)

**EUROPEAN PATENT APPLICATION**

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(30) Priority: **03.05.2000 EP 00201596**

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**1800 Vevey (CH)**

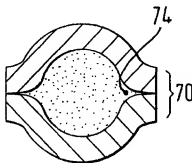
Remarks:

The biological material has been deposited with  
CNCM under number(s) I-1225, I-2116, I-2170,  
I-2169, I-2168 and with ATCC under number 2753

**(54) Confectionery product having a filling**

(57) The invention relates to a confectionery product which comprises at least one functional ingredient wherein it has a casing and a filling enclosed within the casing wherein the filling comprises at least one confectionery material having properties that confer to the filling a perceivable effect when the filling is released in

the mouth; wherein the casing is capable of forming release means upon the action of the saliva in the mouth which acts to liberate the filling out of the casing and wherein the enable the casing to be left substantially as an empty shell before it has entirely dissolved in the mouth.

**FIG. 2****EP 1 151 673 A2**

## Description

**[0001]** The present invention relates to a novel confectionery product capable of providing a pleasant and rapid release of a confectionery material to the consumer. More specifically, the invention relates to a confectionery product capable of delivering at least one functional ingredient in a pleasant and perceivable manner. The present invention also relates to a method for releasing functional ingredients from a confectionery product providing a perceived well-being effect which increases consumer acceptance.

**[0002]** A number of attempts have been made to encapsulate or retain functional ingredients into various glassy, sintered or chewy matrixes. In general, the confectionery serves as a solid continuous matrix for the functional ingredient. The functional ingredient is delivered according to the dissolution rate of the confectionery matrix which confers a solid taste in the mouth. Crushing the confectionery is a solution for the consumer to speed up the release of the functional ingredient but this solution may be undesirable as dental problems may arise and/or the release rate of the functional ingredient may not be respected as recommended. Depending upon the method of manufacturing the confectionery matrix, the functional ingredient may suffer from deterioration or damages due to heat and/or mechanical stresses in the manufacturing process. The method which consists in overdosing of the functional ingredients in the confectionery matrix to overcome a high deterioration rate due to strong processing conditions is a costly method. The "solid" taste a pressed tablet or glassy matrix may provide in the mouth may also be considered as not very attractive in the context of delivering active ingredients, especially if the product is supposed to be primarily a confectionery.

**[0003]** Liquid filled boiled sweets are known. They may also be used to deliver functional ingredients. However, despite the fact the centre is primarily liquid, the whole product has a tendency to melt as one piece in the mouth while the centre does not release from the casing rapidly but melts slowly and progressively thus making a pasty mass.

**[0004]** Powdered sugar filling in a high boiled sweet is also known for many years to make traditional confectioneries such as "Sherbet Lemon" in England. However, such a sweet has not been used for delivering functional ingredients. Furthermore, it behaves in the mouth in a way similar to the liquid filled boiled sweets with the casing and filling melting slowly in the mouth; a significant part of the filling agglomerating within the casing in contact with the saliva thus forming lumps which remain in the casing during the dissolution of the casing.

**[0005]** In the domain of the encapsulation of functional ingredients, we may cite the following publications as pertaining to the general background. US patent 5,897,897 relates to encapsulation of medications, pes-

ticides, vitamins, preservatives and flavouring agents within a glassy matrix consisting of modified starch and polyhydric alcohol. EP 0904 784 discloses a probiotic preparation with health promoting action comprising bacteria cells, novelose, arabic gum included in a 3-gram proteinic capsule. US patent 5,648,092 relates to pharmaceutical compositions in the form of pleasant-tasting chewable tablets or chewable coated tablets which besides the pharmaceutically active ingredient sulfacrate, essentially contain at least one rapidly swellable physiologically acceptable gel former plus sugar or sugar substitutes. US 4,396,631 describes a bifidobacterium-containing confectionery tablet including one or more of substances selected from the group consisting of starch, starch hydrolyzate and protein. JP 2893021 relates to a boiled sweet enclosing bifidobacteria encapsulated with a protective coating film and diluted with a mixture of powdered sugar or sugar alcohol as a filling. JP 60083535 relates to a preparation of candies containing lactobacilli activated with spores made by mixing sugar and millet honey, chilling, pulverising and adding activated lactobacilli powder. JP 57032221 discloses candy tablets containing bifidus microorganism made by mixing microorganism powder with fat, adding further raw materials and tableting. EP 704164 discloses a confectionery composition containing a long-life lactic bacteria, fats and/or oil, fermented milk powder and saccharide. DE 19830528 discloses a multi-layer tablet comprising nutritious substances and microorganisms and can be stored without cooling.

**[0006]** Confectionery technology, in particular sugar-based confectionery, also suffers from a negative image of providing very little positive effect on nutrition and health. In the meantime, in the recent well-being oriented boom, there is an increasing general concern and consciousness of people relating to food and what should be the true and genuine function of food with respect to health and nutrition. The known products on the market are far from reaching the consumer's expectations in term of taste, sensation in the mouth and appearance. In particular, many known functional ingredients have no particular flavour or even off-flavour that make the product carrying the functional ingredient(s) unpleasant to consume.

**[0007]** Therefore, it has been realised that at least part of the commercial success of a well-being oriented product is a question of how the product releases in the mouth. The consumer must have the sensation that something remarkable and perceivable appears in the mouth that send him signals that a functional activity takes place and preferably in a pleasant and tasteful manner.

**[0008]** A primary object of the present invention is to propose a genuine confectionery product that provides a perceivable sensory effect in the mouth as an indicative signal of the delivery of one or more functional ingredient(s).

**[0009]** Another object of the present invention is to

provide a confectionery product that confers a sudden rapid and perceivable release in the mouth of a confectionery material without necessarily having to chew or bite in the confectionery product.

[0010] Another object is to induce an effect of well-being in consumers.

[0011] Another object is to increase of consumer acceptance of functional confectionery products.

[0012] Another object of the invention is to offer alternative carriers in a same confectionery product for the functional ingredient(s) depending upon how fast the functional ingredient(s) needs to be orally delivered.

[0013] Another object is to offer the possibility to deliver functional ingredients at different speeds in the mouth, for example, either to confer a sustained release effect or to separate the delivery time of functional ingredients having different active effects, sensations and/or flavours.

[0014] Accordingly, the present invention provides a confectionery product which comprises at least one functional ingredient wherein it has a casing and a filling enclosed within the casing wherein the filling comprises at least one confectionery material having properties that confer to the filling a perceivable effect when the filling is released in the mouth; wherein the casing is capable of forming release means upon the action of the saliva in the mouth which acts to liberate the filling out of the casing. Furthermore, the confectionery material has dissolution properties effective to act together with the release means to enable the casing to be left substantially as an empty shell before it has entirely dissolved in the mouth.

[0015] Therefore, the confectionery product has the remarkable ability to provide a release of a filling in a perceivable manner upon the action of the saliva which dissolves in the mouth while the casing has not entirely melted.

[0016] The invention also relates to a functional confectionery product which comprises:

- at least one functional ingredient for providing a functional benefit to a consumer;
- a filling which includes at least one sensory agent having properties that confer to the filling a perceivable sensory effect in the mouth indicative of functional release; and,
- a casing enclosing the filling and which dissolves slower than the filling, the casing further having release means activated by saliva for releasing the filling from the casing.

[0017] The invention also relates to a method for improving consumer acceptance of a confectionery product containing a functional ingredient, the method comprising incorporating into the confectionery product a sensory agent producing a perceivable sensory effect in the consumer's mouth indicative of functional release.

[0018] The invention also relates to a method for in-

ducing an effect of well being in a consumer, the method comprising administering to the consumer a confectionery product which contains a functional ingredient and a sensory agent which produces a perceivable sensory effect in the consumer's mouth indicative of functional release.

[0019] The invention will now be described in greater details in the following description.

Fig. 1 shows a perspective view of a filled sweet of the invention;

Fig. 2 shows a cross sectional view of the sweet of fig. 1 along line A-A;

Fig. 3 illustrates a preferred process for producing the filled sweet of fig. 1 and 2;

Fig. 4 shows a cross-section view of the sweet of fig. 1 after partial melting of the casing in the mouth thus producing a rapid release of the filling;

Fig. 5 shows a cross-section view of the sweet according to a variant of the invention;

Fig. 6 shows a cross-section view of a sweet according to another variant of the invention in which the casing has a tubular and substantially annular shape;

Fig. 7 is a graph of the profile of the cumulative weight loss over time according to the dissolution test of Example 4;

Fig. 8 is a graph of the profile of the differential weight loss over time according to Example 4.

[0020] The present invention provides a novel confectionery product that provides a perceivable sensory effect in the mouth as an indicative signal of the release of one or more functional ingredients. This increases the consumer's belief of functionality and improves the consumer's feeling of well being. The invention preferably comprises a casing and a filling where the filling has a confectionery sensory agent.

[0021] Preferably, the filling of the confectionery product comprises at least one confectionery carrier or sensory agent that has the capability to flow out of the casing while conferring a remarkable effect in the mouth that will make the filling clearly perceivable upon release in the mouth. In a preferred embodiment, the confectionery carrier is a powdered anhydrous mass having high dissolution properties giving the ability to flow out of the casing through passage means formed upon contact of the product with saliva and rapidly dissolves in the mouth.

[0022] Even more preferably, the carrier is selected from the group of polyols having both a cooling and "liq-

uid" effect in the mouth provided by a high dissolution enthalpy. Indeed, it has been surprisingly found that when a crystalline powdered carrier in the form of such a polyol is released from the casing by passage means, one may obtain a higher dissolution ratio of the filling in the mouth with both a "liquid" and cooling effect. The rapid dissolution positively effects the way the filling leaves the casing. This feeling of having a "liquid" feeling provided by dissolution effect differentiates from the solid feeling usually provided by compressed tablets or glassy sweets. This feeling also differentiates from liquid feeling merely provided by liquid or viscous cores which release less rapidly and confer a syrupy feeling. The effect is also preserved by the fact the polyol is kept from a thermodynamic point of view, in a very stable and efficient state over time, as it may be efficiently protected from environment by the confectionery casing and especially from moisture ingress during the storage period.

[0023] A perceivable effect in the mouth is emphasised by providing release means that has the function of enabling the filling to rapidly and fully leave the casing thus giving the signal in a pleasant and tasteful way to the consumer that a filling is progressively liberated in the mouth before the casing has entirely melted. As a preferred embodiment, the release system comprises at least one small hole and/or zone of reduced thickness provided in the casing which is capable of forming at least one outside passage communicating with the filling. When zones of reduced thickness are provided in the casing, the passage means are formed after the confectionery product has been maintained in contact with the saliva during a few seconds. Preferably, passage means are formed after a lag time of from 5 to 120 seconds, even preferably of from 10 to 40 seconds to enable the release of the filling. The passage means are important to prevent a significant dissolution of the casing before the filling is released which otherwise would not confer the well-being effect that is sought indicative of functional activity for the consumer. To some extent, the passage means also reduces the consumer's desire to bite to the centre as the consumer can feel the progressive release of the filling. It is also believed that the passage means also participates to an improved consumer acceptance of the functional delivery.

[0024] Preferred polyols which may be used as a powder carrier are those which have a high negative heat of solution. The heat of solution is a thermodynamic expression to define the amount of heat a solution requires to dissolve one gram of solute. In the case of polyols having a perceivable cooling effect, energy is given off by the solution so as to make the heat of solution negative. The polyols of the invention have generally a heat of solution of less than -25 cal/g, preferably less than -30 cal/g. As a matter of comparison, sucrose is known as having a heat of solution of -4 cal/g only. When the filling is contacted by saliva in the mouth, a thermodynamic reaction between the anhydride polyol and the saliva occurs instantaneously and dissolution takes

place thus conferring the impression that the powdered filling is a cool "liquid". It is also preferred that the solubility of a polyol for the filling is relatively high. More particularly, the solubility should preferably be higher than 240 g/100 g of water at 37°C. The higher the solubility, the more "liquid" the filling feels. However, the confectionery material for the filling should be soluble but not too hygroscopic as this would possibly cause formation of lumps in the casing which prevents the filling from leaving the casing upon action of the saliva.

[0025] The confectionery material for the filling is preferably in a fluid powdered state within the casing; i.e., that is not in a self-cohesive solid, pasty or liquorous state within the casing, thus giving the filling the ability to flow freely from the casing through a passage provided in through the casing. The fresh "liquid" effect is indeed also dependent on the flow properties of the powder when leaving the casing. The quicker a significant amount of the powder can discharge in the mouth, the greater an exploding fresh liquid effect is perceived, as the powder is immediately available to melt in contact with the saliva. The filling should not be agglomerated or pressed to make a self-cohesive mass within the casing, as the release of the filling would be delayed until the casing has almost entirely melted, thus conferring a more "solid" taste similar to the taste of crystallised polyol coatings.

[0026] A suitable monosaccharide polyol is preferably selected from the group consisting of xylitol, erythritol, sorbitol or a combination thereof. Xylitol is preferred as, based on the applicant's experiments, it is one of the polyols that tasted the most "liquid" and fresh, at the same time, upon release in mouth therefore giving an attractive perceivable effect in its function of releasing the functional ingredient(s). It also has a medium-range solubility which makes it both very reactive but also capable of sustaining an extensive period of storage within the casing of the invention without making lumps. Xylitol has a heat of solution of between -30 to -45 g/cal depending upon the chemical purity of the product (for instance, the commercial product Xylisorb® supplied by Roquette Frères of Lille, France is -34.8 g/cal). Solubility of xylitol is about 250-260 g/100 g of water at 37°C whereas sucrose has a solubility under 230 g/100 g and maltitol has a solubility of less than 205 g/100 g. Sorbitol has a higher hygroscopicity and a water solubility of about 330-340 g/100 g (37°C) but a lower heat of solution in the range of -28 to -26 g/cal. Sorbitol is supposed to have a slightly higher cooling effect than xylitol which can be measured by the instant fall of temperature when a determined amount of powder is added to water. The measured cooling effect of sorbitol is about -22 °C whereas xylitol is about -20°C (Instant fall of temperature when 150 g of powder are added to 50 ml of water at 37°C). However, in practice, it has been noted that xylitol provides a sharper combined "liquid" and fresh sensation in the mouth than sorbitol. Anhydride crystals of Erythritol differ from other polyols in that they are less



water soluble but have a very low negative heat of solution of about -42 to -45 g/cal which confers a relatively weaker "liquid" feeling but a still a cool sensation in the mouth.

[0027] The control of the granulometry of the powder has also proved to be important for enhancing the cooling effect as well as for speeding up the emptying of the casing through the passage means and the reaction of dissolution in the mouth. The finer the particles of powder, the more the release of the polyol mass tastes "liquid" with no gritty sensation in the mouth. Finer free flowing particles promote the surface of contact of the polyol substrate with liquid during release which consequently concentrates the heat exchanges in a much shorter period of time. More specifically, substantially at least 85 % by weight, preferably at least 95 %, even more preferably 100% of the particles have a size preferably less than 250 microns. More preferably, at least 30 % by weight, preferably 40 wt. %, of the particles have even less than 100 microns. A suitable example of particle size distribution is: less than 0.1 wt. % of more than 500 microns, less than 1.2 wt. % of between 500 to 250 microns, less than 48 wt. % of between 250 to 100 microns and the remainder of less than 100 microns.

[0028] The confectionery carrier or sensory agent may comprise ingredients selected to provide a sensory effect complementary to the functional ingredient. For example, if the functional ingredient is a stimulant such as caffeine, the sensory agent may contain effervescent substances (eg, bicarbonate) to enhance the stimulation. Similarly, if the functional ingredient is a calming substance such as valerian, the sensory agent may contain soothing substances to enhance the calming effect.

[0029] The confectionery carrier in the filling consists essentially of an anhydride polyol as aforementioned. However, a small amount of other ingredients might be added to flavour and/or sweeten the filling or to overcome an off-taste of the pure functional ingredient(s) when necessary. In particular, natural or artificial flavouring agents may be used. Spray-dried and freeze-dried fruit juice such as lemon, orange, strawberry or others, may advantageously be added in an amount lower than 20% by weight, preferably lower than 12% by weight of the filling. Acids may also be added such as citric acid or maleic acid in amount preferably in the range of 0.1 to 3% by weight of the carrier.

[0030] Preferably, the amount of the confectionery carrier in the filling should be effective to produce the sensory effect; e.g., both a "liquid" and cooling effect that is sought. Therefore, the content of non-polyol in the filling should not exceed 50% by weight of the filling. Therefore, the amount of polyol with the intended cooling effect should be of at least 50%, preferably 70%, even preferably at least 85% by weight of the filling; the rest being functional ingredient(s) and/or flavouring and/or other ingredient(s).

[0031] The invention also provides the possibility to use either the filling or the casing as a carrier for the

functional ingredient(s) depending upon the particular needs. In particular, if it is required to rapidly deliver the functional ingredient(s) in the mouth; e.g., for clinical, sensitive and/or flavour reasons, the filling is preferably the carrier for the functional ingredient(s). Alternatively, when there is a need for delaying the delivery of the functional ingredient and/or provide a sustained release of the functional ingredient(s), the casing may be the carrier for the functional ingredient(s). In another embodiment, when there is a need to deliver functional ingredient(s) at different speeds in the mouth, both the filling and the casing may serve the function of the carriers for the functional ingredient(s). In that particular case, both carriers may have the same functional ingredient(s) or alternatively both carriers may have different functional ingredients. For example, different functional ingredients may require to be stored separately in the confectionery and delivered at different dissolution rates to optimise their efficiency, prevent inhibitory effects and/or degradation, and/or offer improved sensations and/or flavours.

[0032] Within the context of this specification, the term "functional ingredient" refers more particularly to the IL-SI European definition that states that a functional food can be regarded as "functional" if it is satisfactory demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects in a way that is either an improved state of health and well-being and/or reduction of risk of disease (Scientific Concept Of Functional Foods In Europe: Consensus Document, British Journal Of Nutrition, Volume 80, supplement 1, August 1998). In particular, functional ingredients are nutritive substances that can be added to foods in controlled quantities in order to fulfill a specific physiological function or promote the health and well-being of the consumer. The functional ingredients may include ingredients having active effects in dental or medical hygiene, bone health, digestive aid, intestinal protection, general nutrition, performance nutrition, stress relief, throat soothers, breath fresheners, etc.

[0033] According to a preferred embodiment of the invention, the confectionery product includes at least one functional ingredient chosen among the list consisting of probiotic bacterium, prebiotic, vitamin, enzyme, antioxidant, mineral salt, amino-acid supplement, peptide, protein, gum, carbohydrate, phytochemical, dextrose, lecithin, other trace nutrient, brain-stimulating substance, energy provider, a mineral, mineral salt, botanical extract, fatty acid, oat beta glucan or other functional fibre, creatine, carnitine, bicarbonate, citrate, caffeine or any mixture thereof. The functional ingredient(s) may be enclosed within the filling and/or within the casing. Many functional ingredients are thermosensitive compounds such as the probiotics or vitamins that degrade upon heating them at temperatures higher than about 70-80°C. Depending upon the manufacturing method, the material for the casing may reach such temperatures levels or go even beyond during the cooking stage.

Therefore, the powdered carrier in the filling has been found to be an effective means for successfully insulating the functional ingredient(s) keeping the functional ingredient(s) alive and/or active after encapsulation into the confectionery casing. Even more surprisingly, it has been found that polyols selected from the ones having a low heat of solution, such as xylitol, had the ability to protect the heat sensitive functional ingredients during the step of encasing with a melted material for the casing. In particular, tests have shown that heat sensitive functional ingredients, such as microorganisms, can be encased within the casing while the microorganisms can resist the heat encasing with no significant mortality. Furthermore, the functional ingredient does not need to be specifically treated beforehand as, for instance, there is no need for encapsulation or microencapsulation of the microorganisms with a protective film coating thus saving a step in the production.

[0034] Thermosensitive functional ingredients that may be used in the present invention typically include probiotic microorganisms in the form of live microbial feed supplement(s) which are recognised as conferring a beneficial effect for human beings. Probiotic microorganisms are micro-organisms which beneficially affect a host by improving its intestinal microbial balance (Fuller, R; 1989; J. Applied Bacteriology, 66: 365-378). There are a variety of probiotic microorganisms which are suitable, in particular, having regard to activation of the immune system, prevention of the bacterial overgrowth by pathogens, prevention of diarrhoea and/or restoration of intestinal flora. Probiotic microorganisms includes yeast such as *Bifidobacterium*, *Lactobacillus*, *Streptococcus*, *Saccharomyces*. Preferably, the microorganism is in a spray dried or freeze-dried form.

[0035] More preferably, said probiotic bacterium may be selected from the group consisting of *Lactobacillus johnsonii*, *Lactobacillus paracasei*, *Bifidobacterium longum* B129, *Bifidobacterium longum* B128, *Bifidobacterium adolescentis* Bad4, and *Bifidobacterium lactis* Bb12. The strains were deposited by way of example under the Budapest Treaty at the Collection Nationale de Cultures de Microorganismes (CNCM), Institut Pasteur, 28 rue du Docteur Roux, 75724 Paris Cedex 15, France except for *Bifidobacterium lactis* Bb12.

[0036] *Lactobacillus johnsonii* (NCC 533) has been deposited on the 30.06.1992 under reference CNCM I-1225, *Lactobacillus paracasei* (NCC 2461) has been deposited on the 12.01.1999 under reference CNCM I-2116, *Bifidobacterium longum* (B129) (NCC490) has been deposited on 15.03.1999 under reference CNCM I-2170, *Bifidobacterium longum* (B128) (NCC481) has been deposited on 15.03.1999 under reference CNCM I-2169, and *Bifidobacterium adolescentis* (Bad4) (NCC251) has been deposited on 15.03.1999 under CNCM I-2168. *Bifidobacterium lactis* (Bb12) may be obtained at Hanzen A/S, 10-12 Boege Alle, P.O. Box 407, DK-2970.

[0037] The amount of probiotics may vary according

to the specific needs. However, in a preferred embodiment, the amount of lactic acid bacterium in one piece of confectionery product is  $10^2$  to  $10^{12}$  count/gram, more preferably from  $10^7$  to  $10^{11}$  count/gram, even more preferably  $10^8$  to  $10^{10}$  count/gram. The amount per gram of bacterium in one product is preferably determined upon the recommended daily dosage based on the number of products to be consumed per day.

[0038] Preferably, prebiotics may also advantageously be used alone or in combination with the probiotic bacteria in the confectionery product. Prebiotics comprise carbohydrates and more specifically oligosaccharides. Prebiotics of this kind have the ability to resist hydrolysis by enzymes of the human digestive tract, can reach the colon undegraded and provide a carbohydrate substance particularly suited to growth of probiotic bacteria. Oligosaccharides may be produced from glucose, galactose, xylose, maltose, sucrose, lactose, starch, xylan, hemicellulose, inulin, or a mixture thereof. Purified commercially available products such as fructooligosaccharide contain greater than about 95% solids in the form of oligosaccharides. In a preferred embodiment, the prebiotic comprises a mixture of fructooligosaccharide and inulin. Preferably this mixture comprises PREBIO1® or a mixture of commercially available RAFTIOSE® and RAFTILINE® commercialised by Orafit. A prebiotic of this kind has proved to improve the response of the immune system.

[0039] Other suitable functional ingredients comprise vitamins and minerals that the body is usually not capable of synthesising and which are necessary for ensuring normal growth and/or daily body maintenance. Both hydrosoluble or liposoluble vitamins may be used as functional ingredients in suitable amounts. The vitamins are preferably included in the filling as they usually are sensitive to light, oxygen and/or heat. A list of vitamins that may be used is not limiting and includes: Vitamin A (axerophthol or retinol), Vitamin D, Vitamin E (alpha-tocopherol), Vitamin K, Vitamin B and/or PP (niacin or nicotinic acid) and Vitamin C (L-ascorbic acid). The thermosensitivity of vitamins may vary in a wide range. For instance, vitamin B1 is highly thermosensitive whereas vitamin B3 (niacin) can resist very high temperatures without damage. Vitamins A, B2, B6 and C are also photosensitive and should therefore be included in the filling for a longer shelf stability. Vitamins A, B1, B6 and E are oxygen sensitive and therefore should also be included in the filling for a longer shelf stability. The dosage of vitamins in the confectionery may be adapted to the specific needs. Preferably, one product may contain a fraction of the recommended daily amount (RDA) of the desired functional ingredients. For instance, assuming a five sweets daily consumption, and following European RDA recommendations, preferably, Vitamin A should be used as up to 160µg preferably between 70µg and 90µg a single sweet; Vitamin C as up to 12 mg preferably between 5 mg and 7 mg a single sweet; Vitamin E as up to 2 mg preferably between 0.8 mg and 1.2 mg a single

sweet; Vitamin D as up to 1 µg preferably between 0,4µg and 0,6 µg a single sweet; Vitamin B1 as up to 0,28mg preferably between 0,12mg and 0,15mg a single sweet.

[0040] Antioxidants can be used for the functional ingredient, alone or in combination with other functional ingredients, such as for example: glutathione, peroxidase, superoxide dismutase, catalase, co-enzyme Q10, honey, tocopherols, beta-carotene or other carotenoids, quercetin, rutin, flavonoids, catechins anthocyanes, eleuterosids and ginsengoids. Actually, a few of these antioxidants may be found in significant amounts in plant extracts. Examples are Ginkgo Biloba leaves which contains Ginkgo flavonoids, Blueberry fruits which contains anthocyanids, Ginseng roots which contains ginsengoids, Eleuterococcus roots which contains eleuterosids. The functional ingredient may also be a phytochemical chosen among the group consisting of polyphenol, procyanidin, phenolic acid, catechin or epicatechin, isoflavone, terpene or other phytonutritive plant material.

[0041] Preferably, suitable minerals as functional ingredients include macro-nutrients such as Sodium, Potassium, Calcium, Magnesium, Phosphorus or oligo-elements such as Iron, Zinc, Copper, Selenium, Chromium, Iodine. Macro-nutrients are known to play an essential role in complex metabolisms of the body such as in cellular cation exchange. A preferred macro-nutrient is calcium which is an essential constituent of the skeleton. Following EU RDA recommendations and assuming, for instance, an average daily consumption of 5 confectionery products, Calcium may be used in amounts of up to 160 mg, preferably between 60 mg and 90 mg a single product.

[0042] Trace elements are minerals present in the human body in quantity of usually less than 5g. Zinc is a preferred mineral as its helps compensate for its increased losses during oxidative stress, it has antioxidant properties and help synthesis of metallothionein, it is an essential factor for protein synthesis and helps improve the function of the immune system. Following EU RDA recommendations and assuming a daily consumption of 5 confectionery products, Zinc may be used in amounts of up to 3 mg a product, preferably between 1,3mg and 1,7 mg.

[0043] Selenium is also a preferred mineral for its antioxidant properties and is a co-factor for glutathione peroxidase. Selenium is also known to contribute to the integrity of muscles and sperm and also plays a role in hepatic metabolism. Selenium deficiencies may lead to severe cardiac, bone or neuro-muscular damage. Preferably, following the European RDA recommendations and assuming a daily consumption of 5 confectionery product, Selenium may be used in amounts of up to 11 µg a sweet, preferably between 4 µg and 6 µg.

[0044] Preferably, active nutrients for the functional ingredient may include amino-acids, di-peptides or polypeptides or proteins or essential fat acids. A suitable example of an amino-acid is glutamine which provides the

advantage of providing fuel to gastrointestinal and immune cells, reduces bacterial translocation and helps prevent muscle loss and improves nitrogen balance.

[0045] Preferred examples of peptides are the glycopeptides of lactic origin active in inhibiting the adhesion of the bacteria responsible for dental plaque and caries. More particularly, dental and anti-plaque caries agents of this types comprise active principle(s) selected from kappa-caseino-glycopeptides and desialylated derivatives thereof (also known as "CGMP"). Such active principles have an effectiveness on the dental plaque only after a few seconds in the mouth. Therefore, due its rapid release and dissolution rate, the filling is particularly suitable for serving as a carrier for these glycopeptides. A detailed description of these active glycopeptides is given in the European Patent 283675; the content of which is incorporated herewith by reference. Other peptides may also be a phosphopeptide or a salt thereof having anticaries properties such as those having from 5 to 30 amino acids including the sequence A-B-C-D-E where A, B, C, D and E being independently phosphoserine, phosphothreonine, phosphotyrosine, phosphohistidine, glutamate and aspartate and compositions particularly compositions to teeth including same. A detailed description of those phosphopeptides is provided in US Patent 5,015,628.

[0046] Other examples of a polypeptides are cystein, acetylcysteine, cystine methionine or a mixture thereof. Cystein and its derivatives are known to provide advantage of aiding defence oxidative stress and aid protein synthesis.

[0047] Other active nutrients may be functional fibres or phospholipids.

[0048] Further examples of active chemicals are caffeine known as a CNS stimulant and obtained as a by-product of coffee or tea extraction process.

[0049] Preferably the functional ingredient may advantageously be taken from the category of botanical extract is selected from the group consisting of Guarana, Ginkgo Biloba, Kola nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. John's Wort, Valerian and Ephedra, beta-sitosterol, caffeine, cafestol, D-limonene, kabweol, nomilin, oltipraz, sulphaphane, tangeretin, black tea, white tea, java tea, folic acid, garlic oil, fiber, green tea extract, lemon oil, mace, licorice, menthol, onion oil, orange oil, rosemary extract, milk thistle extract, Echinacea, Siberian ginseng or Panax ginseng, lemon balm, Kava Kava, matte, bilberry, soy, grapefruit, seaweed, hawthorn, lime blossom, sage, clove, basil, curcumin, taurine, wild oat herb, dandelion, gentian, aloe vera, hops, cinnamon, peppermint, grape, chamomile, fennel, marshmallow, ginger, slippery elm, cardamon, coriander, anise, thyme, rehmannia, eucalyptus, menthol, kava kava, schisandra, withania, cow-slip, lycium, passion flower.

[0050] In a preferred aspect, the filling part should represent between 6 to 30 % by weight of the whole confectionery product including the casing part, more pref-

erably, 8 to 22 % by weight, and even more preferably 11 to 18 % by weight. The maximum amount of filling has proved to be a limiting factor for two main technical reasons. A first reason is due to the process difficulties that have been experienced for encasing the filling with a too high proportion of powder when using the conventional die forming method. If the casing is not sufficiently closed, the powder may leak out from the casing during storage thus causing a poor reactive effect upon consumption due to the lack of powder left in the casing. A second reason for a limited proportion of the filling is that the casing is also weakened with a too small thickness of the walls that might cause the fracture of the casing, in particular upon packaging of the product, if no very special attention is paid, that would lead to an increase of the rate of defective packaged products. On the other hand, if the amount of filling is too low, the casing will be too thick, the release will not form in contact with saliva and the perceivable effect; eg. the liquid and refreshing effect, may be lost or at least seriously weakened. The casing may also be too firmly closed and the release of filling is delayed too much.

**[0051]** The filling may entirely or only partially fill the casing depending upon the size of the casing. For relatively small or medium size sweets, the casing is entirely filled with the filling so as to ensure both the desired liquid and functional effects. The casing has dimensions of usual sweets; i.e., a main weight ranging from 1 to 6 g, and preferably from 1.2 to 3 g.

**[0052]** In a preferred aspect of the invention, the casing of the confectionery is a boiled sweet, also commonly called hard sweet or high boiled candy which is a solid, glassy and amorphous casing. The casing may contain only sugar alcohols. In that case, the confectionery is thus entirely sugar-free, non cariogenic and low calorie which also makes it suitable for children, elderly people, diabetic or in dental hygiene or breath freshness. The sugar alcohols for the casing can be of any commercially available, economically satisfactory, sugar alcohols which are suitable for the production of non-hygroscopic hard candy. The polyalcohols for the casing are preferably selected from the group consisting of isomalt, sorbitol, maltitol, lactitol, mannitol, polydextrose and combination thereof.

**[0053]** Besides the polyalcohols, carbohydrates such as sucrose and hydrogenated glucose syrup or other sugars can also be used in mixture with or in replacement to polyalcohols to make the casing. For instance, the casing may have a carbohydrate composition which is less sticky and has a lower tendency to loose its glassy appearance as described in US patent 5,601,866 for which reference is made herein. Relevant additives such as natural or artificial flavourants, colorants or other active ingredients such as acids or sweeteners can be added in conventional amounts to the composition of the casing.

**[0054]** The final moisture content of the high boiled casing is preferably less than 3% by weight, preferably

of about 2% by weight so as to confer an extended shelf life of the product and efficiently keep the filling dry and reagent.

**[0055]** As already mentioned, the casing should have a sufficient thickness to withstand manipulation and packaging operations without easily breaking or fracturing which would cause loss of powder and consequently would impart no or reduced perceivable effects such as the cooling effect of the xylitol carrier. Preferably, the thickness of the casing is comprised between 1 to 4 mm, and more preferably 1.5 to 2.5 mm. The casing may be formed of one or several layers of different hardness, texture and/or flavors. For instance, it may comprise a hard thin coating covering a softer inner layer.

**[0056]** As "casing", we mean any structure of shell provided at a macroscopic scale (at least one millimeter long) within which a significant amount of filling can be stored. Therefore, the casing may have various shapes such as spherical, ovoid, tubular or annular shapes.

**[0057]** Within the context of the specification, the words "comprises" or "comprising" are taken to mean "includes, among other things". It is not to be construed as "consists of only".

**[0058]** The invention is now illustrated as preferred non-restrictive examples in connection with the appended drawings.

**[0059]** High boiled casings of the invention can be obtained by extensive dehydration of a slurry. Generally, the slurry is made of an aqueous mixture of saccharides and/or polyhydric alcohols which is boiled in suitable proportions in a cooker at a temperature of 130-150 °C, preferably under vacuum conditions, to reach a high final solids content of less than 2.5%, preferably of about 1%. Heat resistant functional ingredients may be added at this stage. For instance, essential oils such as Thyme oil or Propoli may be added as part of the ingredients of the casing without suffering deterioration. After cooking, the cooked mass is poured onto a cold slab to reach a suitable plastic consistency.

**[0060]** As shown in fig. 3, the cooked plastic mass 3 is conveyed to a batch roller 10 in which a cone 30 of the plastic mass is pulled out. The batch roller includes a number of conical rollers 11 depending on the manufacturer's specifications which have the function of forming a continuous rope of plastic mass at the end. A centre filling pipe 40 is positioned in the cone of confectionery and the centre filling comprising metered amounts of polyol carrier and functional ingredient(s) is forced by along the pipe which extends into about two thirds to 90 % of the cone's length. For example, a Batch Former model 7RL with file pipe is commercialised by Nuova Euromec that leaves the batch roller contains the filling 50 of polyol crystal powder and functional ingredient(s).

**[0061]** The powder for the filling comes from an auger 41 to feed the centre pipe 40. The next stage consists in sizing the rope 5 to the desired cross-section by using a rope sizer 6 such as a Ropesizer model 61FL from Nuova Euromec, Machinery Division, 24057 Martignago

(Bg), Italy. Individual confectionery products 7 are cut and shaped from the sized filled rope in a die-forming device 8 such as a chain die like assembly having a high output rate (such as model 52STV from Nuova Eumec). The chain die assembly 8 comprises pairs of half-die members 80 that assemble during the rotation of the chains and punch the filled rope into the individual desired closed shapes. The cut ends of the filled sweet are thus closed or partially closed by punching.

[0062] As aforementioned, the proportion of filling should preferably not exceed 30 % by weight, preferably 22 %, even preferably 18 % by weight, to limit serious closure problems that would lead to accidental leakage of the filling during storage or cause fragility of the casing. A preferred amount for the filling is of from 12 to 15 % by weight of the confectionery product.

[0063] According to the method, at least one zone of reduced thickness and/or even one small hole is produced within the casing to enable the filling to discharge in mouth. Such zone(s) of reduction and/or hole (s) should be capable of forming at least one passage in the casing communicating with the filling of a size effective to allow at least a significant part of the filling to be rapidly freed into the mouth. The zone (s) of reduction may be flattened sills obtained by die pressing of the confectionery rope. The resulting passage(s) is (are) formed after a certain time lag between the introduction of the product in the mouth and the beginning of the release of the filling. The time lag is of from 5 to 120 seconds, more preferably from 10 to 40 seconds depending upon the initial thickness reduction, melting properties of the confectionery material of the casing, etc. Depending upon the size of the passages, the release of the filling is more or less progressive. The passages have also tendency to progressively enlarge thus speeding up the release of filling in the mouth. As the filling continuously contacts the saliva, the dissolution is almost instantaneous. The filling is usually entirely released leaving an empty shell for the casing after the product has been maintained in the mouth for about 30 to 150 seconds, preferably for 30 to 60 seconds.

[0064] Fig. 3 shows zones of reduced thickness 70 as a result of the punching action on the filled rope. As illustrated in Fig. 4, zones of reduced thickness 70 of the casing 73 form weaker zones that solubilize by saliva and before the entire casing 73 has entirely solubilized. Preferably, the reduced thickness ranges of from 0.8 to 0.01 time, preferably 0.5 to 0.05 time the average thickness of the casing. Therefore, in both cases larger passages 710, 711 are left after a few seconds in mouth which finally allow the filling to be freed before the rest of the casing has significantly melted. As a result of this progressive but rapid release of filling including the polyol and active ingredient(s), a very pleasant sensation of cool "liquid" is given off. The remainder of the casing is left as an empty shell capable of providing a sustained release for a functional ingredient. It is important to note that particular tapered shape 74 of the reduced thick-

ness zones at the interface of the two-halves of the casing (FIG. 2). Such a tapered shape of the interior of the casing in this region gives rise to the passages or openings upon sufficient melting of the casing wall.

[0065] Fig. 5 illustrates a confectionery product with small holes 720, 721 opposite each other which are formed within the casing 73. The holes are produced during the die shaping of the casing by providing an appropriate clearance within die parts. The holes are produced during the compression of the forming of the confectionery casing in the chain die unit mainly because of the powder filling which does not allow the cooked mass to close the casing. The size of the holes can be linked to the amount of filling added in the sweet, the more filling the bigger the holes. With a lower filling level the holes can be almost completely closed. Therefore, the hole size may be controlled among other factors by adjusting the amount of powder within the casing. The holes should be of a size adapted to the granulometry of the powder for not allowing significant leakage of the powder in the conditions of storage while still releasing properly upon short contact with saliva. Small holes are holes equal to or less than 250 microns, and preferably equal to or less than 100 microns, within the casing thereby providing to the consumer a genuine impression of active release in the mouth.

[0066] Fig. 6 illustrates a variant in which the casing 73 is obtained from a portion of tube and filled with the filling 8. The tube is shaped so as form a filled ring while leaving two free ends 75 with two small holes 750, 751.

[0067] The shape of the confectionery product is not strictly limited. The product could be shaped into round, square, polygonal forms or elongated bars without departing from the spirit of the invention.

[0068] In a possible alternative, the casing may be formed of a chewy crystallised structure known in the confectionery art as "low boiled" candy such as a fudge, a caramel or toffee. The method for producing the sweets is similar to the method for high boiled candy although the cooking conditions may slightly vary. A paste is to produce a crystallised or non-crystallised high-solids fluid that can be sized into a rope, filled and shaped by means of a die or chain die assembly.

[0069] In another variant, the casing may be made of a chewing gum material. Basically, the chewable gum includes a plasticised rubber or polymer, gum base texturizers and sugar and/or bulk sweeteners such as sorbitol, mannitol, hydrogenated starch hydrolyzates, isomalt and xylitol or any suitable polyalcohols. Flavours can be added to give a taste to the chewable casing which can be compounded to essential oils as it is known in the chewing gum industry. Fruit acids may also be added to the casing composition such as orange, lemon, mint, strawberry or grape to enhance the flavour effect of the casing. High intensity sweeteners can be used to increase the sweet taste such as acesulfame K, aspartame, thaumatin, glycyrrhin or saccharin. The chewing gum casing may be pan coated with sugar or

sugar alcohols to confer a superficial rigid coating.

[0070] The rubber or polymer of the chewing gum may contain synthetic elastomers and/or natural elastomers. Synthetic elastomers may include, but are not limited to, polyisobutylene, isobutylene-isoprene copolymer, polyethylene vinyl acetate, polyisoprene, polyethylene, vinyl acetate-vinyl laurate copolymer or a combination thereof. Natural elastomers may include natural rubber such as latex and guayule, natural gums such as jelutong, lechi caspi, perillo, sorva, balata, etc. The preferred synthetic elastomer and natural elastomer proportions vary depending on whether the chewing gum is a conventional gum or a bubble gum. Plasticisers may include estergums, for example, or other suitable plasticisers well known in the chewing gum industry.

[0071] Texturisers may include magnesium and calcium carbonate, ground limestone, silicate, clay, alumina, talc, titanium oxide, phosphates, cellulose polymers, or a combination thereof.

[0072] Non-limiting examples are described below with percentages given by weight, unless otherwise indicated.

## EXAMPLES

[0073] The following examples further illustrate the present invention.

### Example 1

[0074] A mixture of 80 Kg of isomalt F, 10 Kg of maltitol syrup and 10 Kg of water is cooked under 60% vacuum until reaching a cooking temperature of 155°C. The resulting cooked mass is flavoured, coloured and acidified and cooled down at 70°C. A batch roller equipped with a powder pump is charged with the cooked mass. Xylitol powder having particle size of less than 250 microns (XYLISORB® 90 grade from Roquette, France) and freeze-dried *Lactobacillus Johnsonii* are mixed together and charged into the reservoir of the pump. The probiotic xylitol filling is prepared in the proportion of 100 grams of probiotic culture (at 10<sup>11</sup> count/g) for 100 Kg of xylitol.

[0075] The xylitol and probiotic filling is then pumped into the cooked mass and the sweets are stamped in the chain die equipment. The filling is pumped to reach an amount of about 10 wt % of the total weight of the finished product.

[0076] The initial counting of the probiotic is of 2.10<sup>8</sup> count per gram before incorporating the filling within the casing. A final counting is carried out after the manufacture which gives 7.10<sup>7</sup> count/g thus showing a minor decay of the initial counting.

### Example 2

[0077] The following example has an effect in the reinforcement of the cellular repair and sustainability of

the body vitality. A mixture of 80 Kg of isomalt F, 10 Kg of maltitol syrup and 10 Kg of water is cooked under 60% vacuum until reaching the cooking temperature of 155°C. The cooked mass is flavoured, coloured and acidified and cooled down to 70°C. The mass is charged into the batch roller. Separately, a mixture of xylitol and vitamins powder is prepared according to the following composition : xylitol 98,27% wt%, citric acid 1,5 wt%, vit. B1 0,002 wt %, vit. B2 0,003 wt%, vit. B6 0,006 wt%, colouring 0,2 wt%, flavouring 0,01 wt% and charged into the pump. The powder filling is pumped at about 10 wt % of the overall weight.

### Example 3

[0078] The present example is a confectionery product having antioxidant properties with a repairing effect on cellular damages. The same cooked mass for the casing is produced according to example 1 and 2. A xylitol and vitamins powder is prepared with the following mixture: xylitol 98,285 wt%, citric acid 1 wt%, sodium ascorbate 0,3 wt%, vit. E 0,025 wt%, green tea extract 0,180 wt%, flavouring 0,2 wt%, colouring 0,01 wt%. The powder filling is pumped at about 10 wt% of the overall weight.

### Example 4

[0079] The present example is a confectionery product having anticaries properties and activity on remineralization of enamel of teeth. The same cooked mass for the casing is produced according to example 1 to 3. A xylitol powder and CGMP is prepared with the following mixture: xylitol powder 55.5 wt %, CGMP 42 wt %, mint flavour 2.5 wt %. The powder filling is pumped at about 12 wt % of the overall weight.

### Example 5

[0080] The present example is a confectionery product having activity on body recalcification. The same cooked mass for the casing is produced according to example 1 to 4. A xylitol powder and calcium is prepared with the following mixture: xylitol powder 68.42%, Calcium (fraction obtained from milk) 13.3%, sodium bicarbonate 8.32%, citric acid 6.36%, malic acid 2%, flavour 1.6%. The powder filling is pumped at about 12 wt % of the overall weight.

### Example 6 - Comparative Dissolution Test

[0081] A sweet of the invention and a liquid filled sweet of exactly the same dimensions were submitted to a comparative dissolution test as follows. The sweets were produced with the same cooking parameters and the same sugar recipe for the casing but had a different filling; i.e., a xylitol powder filling in the sweet of the invention as compared to a liquid sugar filling in the case

of the comparative sweet.

[0082] The casing for both sweets consisting of 50 wt % sucrose, 45 wt % glucose, 4 wt % water and 1 wt % citric acid was made in the manner described in the Example 1. The sweet of the invention had a filling of xylitol powder of average size of 90 microns. Comparatively, the filling of the comparative sweet was a liquid filling of a sugar composition and water in relative proportion sufficient to reach a measured value of refractometry of 84 % Brix (similar to a liquid honey). The sugar composition of the liquid filling consisted of 50 wt % sucrose, 25 wt % glucose, 25 wt % invert sugar.

[0083] A panel of six trained persons was chosen to test the dissolution of the sweets in mouth. The panelists had to suck each sweet and respectively weigh each one every 15 seconds until the full dissolution of the sweets including the casing was completed. The dissolution test was repeated three times by each panelist. Each panelist used its "own sucking speed", the evaluation finished when the rest of the dissolved sample was impossible to be weighted. An average dissolution curve for each sample was established based on the overall results.

[0084] Fig. 7 represents the cumulative dissolution curves over time. It shows the final dissolution time corresponding to the highest point of the curves as well as the variation of the weight loss related to the time. As illustrated by the sharper slope of the curve, the sweet of the invention dissolved faster than the sweet comprising a liquid filling. The graph also shows that the sweet of the invention has entirely melted before the sweet of reference.

[0085] Fig. 8 represents the differential dissolution profile consisting of the weight variation related to the precedent weight which illustrates the dissolution speed in the mouth. During the first 20 seconds, the behavior of both sweets is substantially similar which corresponds to the initial melting of the casings. After 20 seconds, the passages in the casings have been made sufficient to leave it open for allowing a potential leakage of the filling in the mouth. Therefore, both the xylitol filling and the liquid filling are offered the possibility to release in the mouth. It is demonstrated in the part of the curve (between about 20 - 35 seconds) that the release of the xylitol filling is much faster than the release of the liquid filling. The xylitol filling has entirely left the casing after about 55 seconds (average time) leaving the casing as an empty shell. In the xylitol filled sweet, the dissolution rate is then stable until the holes diameter are big enough to allow the dissolving liquid; i.e., the saliva, to penetrate easily in the empty casing allowing the dissolution of the casing to carry on from the interior. It is remarkable to notice also that the dissolution rate speeds up again due to the introduction of the saliva within the casing as opposed to the sweet of reference where the dissolution rate is relatively steady and slow showing a simultaneous dissolution of the casing and liquid filling. As a sensory fact, it is noticed that the sweet

of reference with the liquid filling confers a weak and slow liquid release more tasting like a pasty taste. It also does not confer any cooling effect. Also, the casing of the sweet of reference has almost entirely dissolved making small discrete pieces before the liquid centre in the mouth has entirely dissolved. As a matter of comparison, the xylitol filling is liberated and dissolved rapidly in the mouth giving a fine liquid and fresh sensation. When keeping the product in the mouth without chewing, it is surprising to feel the casing empty of the filling while the saliva passing through the enlarged passages.

#### Example 7 - Consumer Acceptance and Well being Test

[0086] A comparative confidential test is conducted with two panels of 12 untrained consumers. All panelists are healthy. The consumers are asked to compare the confectionery products of example 2 and 3 to comparative examples which are identical except that the carrier for the functional ingredients comprises a mixture of sucrose, glucose syrup, flavourings and colourings.

[0087] In one session, the confectionery products are fed to one group of panellists blind and in random order. The panellists are requested to rate the confectionery products in terms of pleasantness and in terms of perceived effectiveness. A large majority of the panellist finds the confectionery products of example 2 and 3 to be significantly more acceptable and pleasant. All panellists identify the products of examples 2 and 3 as products that confer a more perceivable feeling of a release of functional material in the mouth.

[0088] In a second session, the second group of panellist is split into two equal sub-groups. One sub-group is given the confectionery products of example 2. The other sub-group is given the equivalent comparative confectionery product. Both sub-groups are informed of the functional activity. The panellists are asked to use the confectionery products according to the RDA recommendations over a period of 30 days. After 30 days, the panellists are interviewed to determine their general well being and feelings of health. The panellists consuming the confectionery products of example 2 express a better overall feelings of health and well being. These panellists prefer the confectionery products than those of the other sub-panel.

#### Claims

1. A confectionery product which comprises at least one functional ingredient wherein it has a casing and a filling enclosed within the casing wherein the filling comprises at least one confectionery material having properties that confer to the filling a perceivable effect when the filling is released in the mouth; wherein the casing is capable of forming release means upon the action of the saliva in the mouth

- which acts to liberate the filling out of the casing and wherein the confectionery material has dissolution properties effective to act together with the release means so as to enable the casing to be left substantially as an empty shell before it has entirely dissolved in the mouth.
2. Confectionery product according to claim 1, wherein the confectionery material of the filling is in a powdered anhydrous form.
  3. Confectionery product according to claim 2, wherein the confectionery material of the filling is chosen so as to confer an instantaneous liquid and cooling effect when released in the mouth.
  4. Confectionery product according to claims 1 or 2, wherein at least 85 % by weight, preferably at least 95 %, of the particles of the confectionery material of the filling have a size preferably less than 250 microns.
  5. Confectionery product according to claim 1, wherein said release means comprises at least one hole and/or zone of reduced thickness provided in the casing which is capable of forming at least one outside passage communicating with the filling.
  6. Confectionery product according to claim 5, wherein said at least one hole is equal to or less than 250 microns, and preferably equal to or less than 100 microns.
  7. Confectionery-based product according to claim 5, wherein the filling part represents between 6 to 30 % by weight of the whole confectionery product including the casing part, more preferably, 8 to 22 % by weight, and even more preferably 11 to 18 % by weight.
  8. Confectionery product according to any of the preceding claims, wherein said confectionery material of the filling comprises a polyol having a heat of solution of less than -25 cal/g, preferably less than -30 cal/g.
  9. Confectionery product according to claim 8, wherein the polyol is selected from the group consisting of xylitol, erythritol, sorbitol and combinations thereof.
  10. Confectionery product according to claim 1, wherein the filling is entirely released leaving an empty shell for the casing after the product has been maintained in the mouth for about 30 to 150 seconds.
  11. Confectionery product according to claim 1, wherein the filling is the carrier for the functional ingredient
  - (s).
  12. Confectionery product according to claim 1, wherein the casing is the carrier for the functional ingredient(s).
  13. Confectionery product according to claim 1, wherein both the filling and the casing are carriers for the functional ingredient(s).
  14. Confectionery product according to claim 1, wherein the filling and casing are carriers for the same functional ingredient(s). Confectionery product according to claim 1, wherein the filling and casing are carriers for different functional ingredient(s).
  15. Confectionery-based product according to any of the preceding claims, wherein said functional ingredient is selected from the group which consists of probiotic bacterium, prebiotic, vitamin, enzyme, antioxidant, mineral salt, amino-acid supplement, peptide, protein, gum, carbohydrate, phytochemical, dextrose, lecithin, other trace nutrient, brain-stimulating substance, energy provider, a mineral, mineral salt, botanical extract, fatty acid, oat beta glucan or other functional fibre, creatine, carnitine, bicarbonate, citrate, caffeine or any mixture thereof.
  16. Confectionery-based product according to claim 15, wherein said probiotic is selected among the group consisting of Bifidobacterium, Lactobacillus, Streptococcus and Saccharomyces.
  17. Confectionery-based product according to claim 15, wherein the prebiotic comprises an oligosaccharide produced from glucose, galactose, xylose, maltose, sucrose, lactose, starch, xylan, hemicellulose, inulin or a mixture thereof.
  18. Confectionery-based product according to claim 17, wherein the prebiotic comprises fructooligosaccharide and inulin.
  19. Confectionery-based product according to claim 15, wherein said peptide comprise a glycopeptide or phosphopeptide having anticaries action.
  20. Confectionery-based product according to claim 15, wherein said vitamin includes Vitamin A (axerophthol or retinol), Vitamin D, Vitamin E (alpha-tocopherol), Vitamin K, Vitamin B and/or PP (niacin or nicotinic amid) and Vitamin C (L-ascorbic acid) and combinations thereof.
  21. Confectionery-based product according to claim 15, wherein said mineral includes Sodium, Potassium, Calcium, Magnesium, Phosphorus, Iron, Zinc, Copper, Selenium, Chromium, Iodine and combina-



tions thereof.

22. Confectionery-based product according to claim 15, wherein said botanical extract is selected from the group consisting of Guarana, Ginkgo Biloba, Kola nut, Goldenseal, Golo Kola, Schizandra, Elderberry, St. John's Wort, Valerian and Ephedra, beta-sitosterol, caffeine, cafestol, D-limonene, ka-bweol, nomilin, oltipraz, sulphoraphane, tangeretin, black tea, white tea, java tea, folic acid, garlic oil, fiber, green tea extract, lemon oil, mace, licorice, menthol, onion oil, orange oil, rosemary extract, milk thistle extract, Echinacea, Siberian ginseng or Panax ginseng, lemon balm, Kava Kava, matte, bil- berry, soy, grapefruit, seaweed, hawthorn, lime blossom, sage, clove, basil, curcumin, taurine, wild oat herb, dandelion, gentian, aloe vera, hops, cin- namon, peppermint, grape, chamomile, fennel, marshmallow, ginger, slippery elm, cardamon, cori- ander, anise, thyme, rehmannia, eucalyptus, men- thol, kava kava, schisandra, withania, cowslip, ly- cium, passion flower.

23. Confectionery-based product according to any of the preceding claims, wherein the casing has a hard glassy texture comprising saccharide or sugar alcohols.

24. Confectionery-based product according to claim 23, wherein the casing consists mainly of at least one sugar alcohol selected from the group consist- ing of isomalt, sorbitol, maltitol, mannitol, lactitol, polydextrose and combination thereof.

25. Confectionery-based product according to claims 1 to 22, wherein the casing is a chewy confectionery material.

26. Confectionery-based product according to any of the preceding claims, wherein the filling is encased into the filling by sizing a filled rope and forming in- dividual casings by stamping the filled rope in a die.

27. Functional confectionery product which comprises:

at least one functional ingredient for providing a functional benefit to a consumer;  
a filling which includes at least one sensory agent having properties that confer to the filling a perceivable sensory effect in the mouth indi- cative of functional release;  
a casing enclosing the filling and which dis- solves slower than the filling, the casing having release means activated by saliva for releasing the filling from the casing.

28. A method for improving consumer acceptance of a confectionery product containing a functional ingre-

dient, the method comprising incorporating into the confectionery product a sensory agent producing a perceivable sensory effect in the consumer's mouth indicative of functional release.

29. A method according to claim 28, wherein the sen- sory agent provides a "liquid" sensory effect ob- tained by rapid dissolution.

30. A method for inducing an effect of well being in a consumer, the method comprising administering to the consumer a confectionery product which con- tains a functional ingredient and a sensory agent which produces a perceivable sensory effect in the consumer's mouth indicative of functional release.

31. A method according to claim 30, wherein the sen- sory agent provides a "liquid" sensory effect ob- tained by rapid dissolution.

32. A method according to claim 29, wherein the sen- sory agent is provided by a filling of the confection- ery product encased in powdered form.

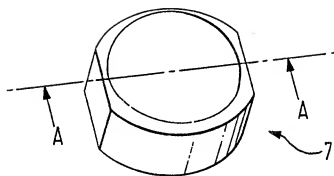


FIG. 1

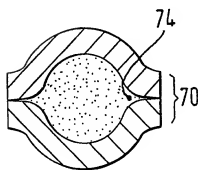


FIG. 2

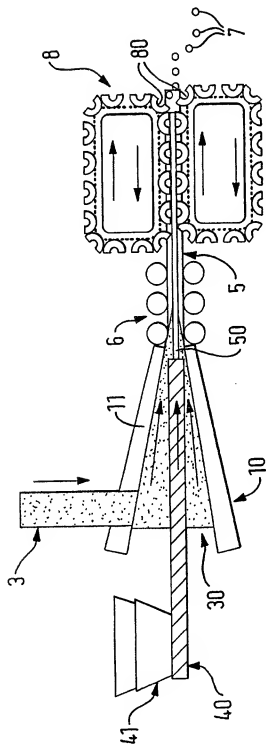


FIG. 3

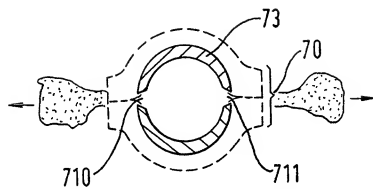


FIG. 4.

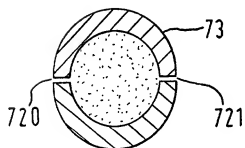


FIG. 5.

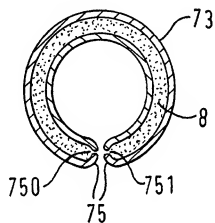
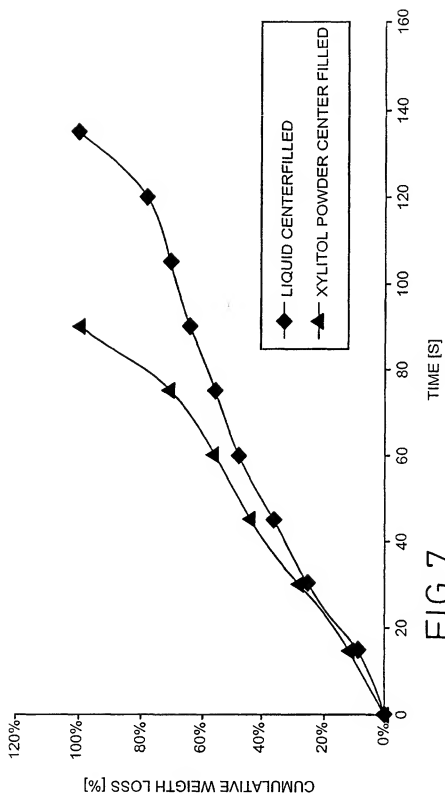
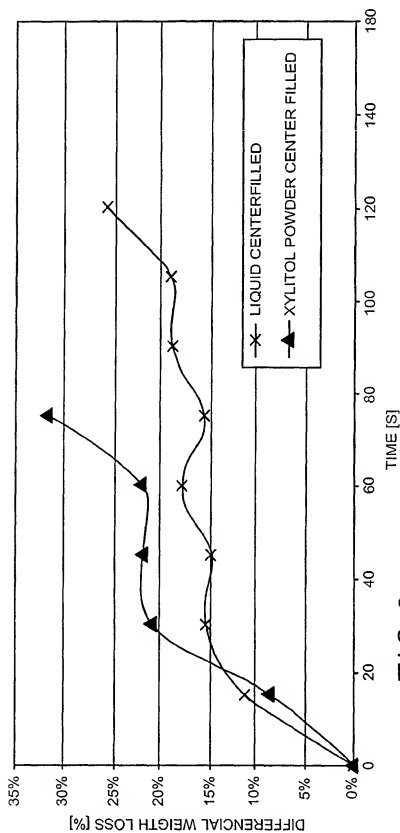


FIG. 6.





# **EXHIBIT D**

[54] SUGARLESS CANDIES

[75] Inventors: Deborah Aldrich, Greenwich, Conn.;  
Walter Vink, Purdys Station; Richard  
W. Deptula, Port Chester, both of  
N.Y.; Donald J. Muskus, Greenwich,  
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Oakland; Marc Chrusch, Cresskill,  
both of N.J.

[73] Assignee: Life Savers, Inc., New York, N.Y.

[21] Appl. No.: 859,784

[22] Filed: Dec. 12, 1977

[51] Int. Cl.<sup>2</sup> ..... A23G 3/00

[52] U.S. Cl. .... 426/658; 426/660;  
426/804

[58] Field of Search. .... 426/660, 548, 804, 658

[56]

## References Cited

### U.S. PATENT DOCUMENTS

|            |        |          |         |
|------------|--------|----------|---------|
| Re. 26,959 | 9/1970 | Conrad   | 426/548 |
| 3,556,811  | 1/1971 | Smith    | 426/660 |
| 3,738,845  | 6/1973 | Liebrand | 426/548 |

*Primary Examiner*—Jeanette M. Hunter

*Attorney, Agent, or Firm*—Lawrence S. Levinson; Merle  
J. Smith; Burton Rodney

[57]

## ABSTRACT

A sugarless candy is provided which has improved flavor and sweetness and contains one or more natural sweeteners, namely, a hydrogenated starch hydrolysate, preferably in combination with a sugar alcohol, such as sorbitol, one or more fruit flavors, together with malic acid which serves as a flavor enhancer.

7 Claims, No Drawings



## SUGARLESS CANDIES

The present invention relates to a sugar-free hard candy of improved flavor and sweetness, but which is free of artificial sweeteners, and more particularly to a sugar-free hard candy containing one or more hydrogenated starch hydrolysates and a sugar alcohol, such as sorbitol as sweeteners, one or more flavors, and malic acid as a flavor enhancer.

Sugar-free sour or fruit-type candies now available generally include an artificial sweetener, usually a saccharin salt, and citric acid and other fruit flavors. However, since the safety of saccharin for human consumption has been seriously questioned, the candy industry is now focusing its attention on non-sugar candies containing natural sweeteners as saccharin substitutes.

Until now, sugar-free, saccharin-free sour candies have been prepared using sugar alcohols, primarily, sorbitol, in combination with citric acid and other fruit flavors. Unfortunately, although such candies deliver a pleasant sour flavor, they are less than satisfactory in providing desired sweetness levels. Attempts to enhance sweetness of such fruit-flavored candies by employing sorbitol in combination with other natural sweeteners, such as hydrogenated starches, have not been successful. It has been found that the citric acid necessary for providing the sour note to the fruit flavor, such as cherry, suppresses sweetness and mask the fruit flavor, imparts distinct citrus overtones in the case of non-citrus flavors, such as cherry and pineapple, and imparts a bland taste in the case of citrus flavors, such as lemon, lime, orange and grapefruit.

U.S. Pat. No. Re. 26,959 to Conrad discloses a sugar substitute which is a hydrogenated starch hydrolysate prepared by hydrogenating a saccharified starch having a dextrose equivalent of 15-75% and containing dextrins, until substantially no dextrose and maltose remain.

Surprisingly, in accordance with the present invention, the above flavor problems associated with the use of citric acid in combination with hydrogenated starch hydrolysates and sorbitol has been resolved by replacing the citric acid with malic acid.

The sour or fruit-flavored sugarless hard candy of the invention consists essentially of one or more hydrogenated starch hydrolysates in an amount within the range of from about 10 to about 99%, and preferably from about 50 to about 98% by weight, one or more sugar alcohols in an amount with the range of from about 1 to about 90%, and preferably from about 1 to about 25% by weight, malic acid in an amount within the range of from about 0.2 to about 5%, and preferably from about 0.5 to about 2.5% by weight. In addition, the candy of the invention may include flavoring, coloring agents, preservatives, and the like.

The sugar alcohols suitable for use herein include sorbitol, xylitol, mannitol, maltitol, and combinations thereof, with sorbitol being preferred.

The hydrogenated starch also referred to as hydrogenated starch hydrolysates employed herein may include those disclosed in U.S. Pat. No. Re. 26,959 as well as various hydrogenated glucose syrups and/or powders which contain sorbitol, hydrogenated disaccharides, tri- to hexa-hydrogenated saccharides, and hydrogenated higher polysaccharides.

The hydrogenated glucose syrups and/or powders may be produced by catalytic hydrogenation of stan-

dard glucose syrups (acid and/or enzyme converted) to the point where all the glucose end groups of the saccharides are reduced to alcohols, that is, dextrose to sorbitol. In the case of hydrogenated glucose syrups, the total solids contents will range from about 72 to about 80% which solids are made of from about 4 to about 20% sorbitol, from about 20 to about 65% hydrogenated disaccharides (that is, maltitol), from about 15 to about 45% tri- to hepta-hydrogenated saccharides, and from about 10 to about 35% hydrogenated saccharides higher than hepta.

The sugarless candy in accordance with the invention may also comprise flavoring agents in an amount of from about 0.01 to about 10% by weight and preferably from about 0.2 to about 0.25% by weight, fruit or mixed fruit flavors.

The sugarless candy may also contain small amounts of coloring agents, preservatives and the like.

Thus, a preferred sugarless candy of the invention may have the following percentage of ingredients:

|                                 |          |
|---------------------------------|----------|
| Hydrogenated starch hydrolysate | 50-98%   |
| Sorbitol                        | 1-25%    |
| Malic Acid                      | 0.5-2.5% |
| Flavoring                       | 0.01-2%  |

The sugarless candy of the invention is prepared by heating, with mixing, a mixture of hydrogenated starch hydrolysates, sorbitol, malic acid and other appropriate additives, such as flavors, coloring agents, preservatives and the like, cooling and then tabletting.

The following Examples represent preferred embodiments of the present invention.

## EXAMPLE 1

A sugarless wild cherry flavored candy having the following composition is prepared as described below.

| Ingredient   | Amount<br>(Parts by Weight) |
|--|-----------------------------|
| Hydrogenated Starch Hydrolysate Syrup<br>(78% solids, including<br>6% sorbitol and 50% maltitol) | 97                          |
| Sorbitol Syrup   | 2                           |
| Malic Acid   | 1                           |
| Cherry Flavor  | 0.25                        |
| Color  | 0.4                         |

The hydrogenated starch hydrolysate and sorbitol syrups are fed into the top of a mixing kettle and are cooled under constant slow agitation to 330°-335° F. The coloring agent is added at 280°-300° F. The mix is dropped at 25" Hg and held under vacuum for 10 minutes. The hot mix is then transferred to a mixing table where malic acid and flavor are added with mixing. The candy mix is allowed to cool to 160°-170° F. and is tabletting. The so-prepared candy is found to have a pleasant cherry flavor which is enhanced by the presence of malic acid.

Control A candy is prepared as described above with the exception that the malic acid is replaced with citric acid. The Control A cherry flavored candy is found to have a distinct undesirable citrus overtone. The citric acid masks the cherry flavor.

Control B candy is prepared as described above in Example 1 with the exception that the malic acid is replaced with tartaric acid. The Control B candy is

found to have a salty and metallic taste due to the presence of tartaric acid therein.

### EXAMPLE 2

A sugarless lemon-flavored candy having the following composition is prepared as described in Example 1.

| Ingredient                                    | Amount<br>(Parts by Weight) |
|---|-----------------------------|
| Hydrogenated Starch                           |                             |
| Hydrolyzate Syrup (as described in Example 1) | 96                          |
| Sorbitol Syrup                                | 2                           |
| Malic Acid                                    | 1                           |
| Flavor  | 0.5                         |

The lemon-flavored candy produced is found to have a pleasant lemon flavor. The malic acid enhances the lemon flavor giving the candy a good initial impact and sustaining lemon flavor.

Control C candy is produced as described above (Example 2) except that malic acid is replaced with citric acid. The Control C candy is found to have a very bland lemon flavor. The citric acid did not enhance the lemon flavor.

Control D candy is produced as described above except that malic acid is replaced with tartaric acid. The Control D candy is found to have a salty and metallic taste due to the presence of tartaric acid therein.

### EXAMPLES 3 to 6

Lime, orange, grapefruit (pink) and sweet pineapple candies containing hydrogenated starch hydrolyzate, sorbitol, malic acid and flavor are prepared as described above.

| Ingredient<br>(Parts by Weight)       | Ex. 3<br>(Lime) | Ex. 4<br>(Orange) | Ex. 5<br>(Grapefruit-pink) | Ex. 6<br>(Sweet pineapple) |
|---------------------------------------|-----------------|-------------------|----------------------------|----------------------------|
| Hydrogenated Starch Hydrolyzate Syrup | 96.6            | 97                | 96                         | 96                         |
| Sorbitol Syrup                        | 2               | 2                 | 2                          | 2                          |
| Malic Acid                            | 1.4             | 1                 | 1.4                        | 1.4                        |
| Flavor                                | 1               | 1                 | 0.4                        | 0.4                        |

Where the Examples 3 to 6 malic acid containing candies are tested against candies of similar composition with the exception that malic acid is replaced with citric acid and tartaric acid, the Examples 3 to 6 candies are vastly superior in taste and sweetness to the control candies.

What is claimed is:

1. A sugarless candy consisting essentially of a hydrogenated starch hydrolyzate in an amount within the range of from about 50 to about 98% by weight, malic acid, and optionally a sugar alcohol.

2. The candy as defined in claim 1 including a sugar alcohol.

3. The candy as defined in claim 2 wherein the sugar alcohol is sorbitol and is present in an amount within the range of from about 1 to about 25% by weight.

4. The candy as defined in claim 1 further including one or more flavors.

5. The candy as defined in claim 1 wherein said malic acid is present in an amount ranging from about 0.2 to about 5% by weight.

6. The candy as defined in claim 1 wherein said hydrogenated starch hydrolyzate includes a mixture of sorbitol and maltitol.

7. The candy as defined in claim 1 wherein said malic acid is present in an amount within the range of from about 0.5 to about 2.5% by weight, and including sorbitol as the sugar alcohol present in an amount within the range of from about 1 to about 25% by weight.

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# **EXHIBIT E**

1

3,738,845

## PROCESS FOR THE MANUFACTURE OF SUGARLESS CONFECTIONS

Jerome T. Liebrand, Farmingdale, N.Y., assignor to Pfizer Inc., New York, N.Y.

No Drawing. Filed Jan. 7, 1972; Ser. No. 216,229

Int. Cl. A23g 3/00

U.S. Cl. 99—134 R

4 Claims

### ABSTRACT OF THE DISCLOSURE

A process for the preparation of clear sorbitol hard candies is described which prevents the crystallization of sorbitol by the addition of an organic acid, such as citric acid, prior to the completion of the cooking step.

### BACKGROUND OF THE INVENTION

This invention relates to a process for preparing confectionery compositions, but particularly to a process for preparing clear sorbitol hard candies.

Sorbitol hard candies are usually made by cooking a commercially available 70% w/w sorbitol aqueous solution at a temperature of at least 300° F.; leaving essentially pure sorbitol. This mass is then cooled to a temperature of about 150° to 200° F. Flavors, coloring agents, gums and organic acids used as acidifiers, for example, citric acid and malic acid, are then mixed in. The mixture is then cast into candy molds and put aside to cool and set until hard. Candies made in this manner tend to exhibit some degree of opacity due to crystallization of sorbitol.

U.S. Pat. No. 3,438,787 discloses a clear confection of sorbitol and mannitol prepared by seeding a substantially anhydrous melt of the ingredients and then allowing the seeded melt to solidify under controlled conditions of temperature and humidity.

### SUMMARY OF THE INVENTION

The present invention discloses an improved procedure for the preparation of hard sorbitol candies which prevents the aforementioned crystallization of sorbitol by addition of an organic acid, such as citric acid, prior to the completion of the cooking step which is carried out to a temperature of at least 300° F.

### DETAILED DESCRIPTION OF THE INVENTION

In accordance with the process of this invention, sorbitol in aqueous solution, usually about 70% w/w., is heated to boiling and the heating is continued with a resulting loss in water until the temperature increases to within the range of 300° to 350° F. At this point a vacuum may be applied to remove any free water in the mass. If desired, heat may also be applied during the vacuum step. The moisture content of the product after cooking is less than 5%.

Prior to heating or at any convenient point during the cooking process, an organic acid, such as citric acid, lactic acid, tartaric acid or malic acid, is added and stirred in. However, the preferred acid is citric acid. The concentration used is preferably from about 0.5% to 5% by weight of the mixture. Normally, therefore, the concentration of organic acid used will be dependent on the flavoring characteristics desired. The acid may be

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added dry, for example, as a powder, or as a concentrated aqueous solution. The exact point during the cooking process at which the organic acid is introduced is not critical, and excellent results are obtained whether it is added at the outset or, say as late as fifteen minutes before the end of the cooking step. Upon cooling, the resulting candies are crystal clear and free from the objectionable opacity or cloudiness usually encountered.

#### Example I

500 gm. of a 70% sorbitol solution were heated to 310° F. in a cooking kettle. To this was then added 10 gm. of citric acid. Vacuum was then applied and the mixture was reheated to 300° F. The mixture was then cooled to 190° F., at which temperature a flavoring agent and coloring agent were added. This mixture was then deposited into candy molds and allowed to reach room temperature, producing a clear hard candy free of crystallization.

#### Example II

Similar results are obtained following the procedure of Example I, using lactic, tartaric and malic acids instead of the citric acid.

#### Example III

Citric acid (5 gm.) was dissolved in 500 gm. of a 70% sorbitol solution and cooked to a temperature of 310° F. Vacuum was then applied and the mixture was reheated to 300° F. The mixture was then cooled to 180° F., at which time flavoring agent and coloring agent were added. The mixture was then deposited into candy molds and allowed to reach room temperature, producing a clear hard candy free of crystallization.

#### Example IV

Citric acid (6 gm.) was dissolved in 500 gm. of a 70% sorbitol solution and cooked to a temperature of 325° F. The mixture was then cooled to 180° F., at which time a flavoring agent and coloring agent were added. The mixture was then deposited into candy molds and allowed to reach room temperature, producing a clear hard candy free of crystallization.

#### Example V

The procedure of Example I was followed using 1.8 gm. of citric acid, with similar results obtained.

#### Example VI

The procedure of Example III was followed using 18 gm. of citric acid with similar results obtained.

#### Example VII

500 gm. of a 70% sorbitol solution were heated to 310° F. in a cooking kettle. The mixture was then cooled to 190° F., at which temperature 10 gm. of citric acid, a flavoring agent and a coloring agent were added. This mixture was then poured into candy molds and allowed to reach room temperature. The resulting hard candy exhibited crystallization of sorbitol on the surface as compared to the candies prepared in the previous examples, which were all free of crystallization.

What is claimed is:

1. In a method of preparing a hard candy composition wherein an aqueous solution of sorbitol is heated at a

temperature of at least 300° F., an organic acid is added in a concentration of from about 0.5% to 5% by weight thereto, and the resultant mixture is cast into candy molds, the improvement comprising blending said organic acid with said sorbitol solution prior to the completion of said heating.

2. The process of claim 1 wherein said acid is selected from the group consisting of citric acid, lactic acid, tartaric acid and malic acid.

3. The process of claim 2 wherein said acid is citric acid.

4. The process of claim 1 wherein said acid is added

## References Cited

## UNITED STATES PATENTS

|           |        |         |          |
|-----------|--------|---------|----------|
| 3,438,787 | 4/1969 | Du Ross | 99-134 R |
| 3,556,811 | 1/1971 | Smith   | 99-134 R |
| 3,632,357 | 1/1972 | Childs  | 99-134 R |

10 ALVIN E. TANENHOLTZ, Primary Examiner

J. M. HUNTER, Assistant Examiner

# **EXHIBIT F**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Cristiana Soldani  
Appl. No.: 11/314,042  
Conf. No.: 5453  
Filed: December 20, 2005  
Title: CONFECTIONERY PRODUCT  
Art Unit: 1761  
Examiner: K. Mahafkey  
Docket No.: 112701-689

**AFFIDAVIT UNDER 37 C.F.R. § 1.132**

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

I am a food technologist (University degree in Food sciences and technologies,  
University of Milan, Italy) and at the moment I am responsible of R&D group in  
The Nestle factory of Perugia, Italy, confectionery  
division.

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2. I am the named inventors of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated February 22, 2007 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the reference cited therein as well as the pending claims.

4. The present invention is directed, in part, to a confectionery product comprising a glassy amorphous solid and having an unexpected and improved transparency that results when

acidic components, which have conventionally been found to hydrolyze the sugar alcohol, are added at the start of the process for the manufacture of the confectionery product under conditions wherein the acid does not hydrolyze the sugar alcohol. In practical terms, this means that acidic components used in the production of a hard candy can be added during the cooking stage of production, which generally involves the use of a vacuum evaporator to reach the desired final moisture content at a temperature which is low enough to avoid hydrolysis of the sugar alcohol. This procedure enables hard candies produced by this process to achieve improved transmission, resulting in hard candies having reduced opacity.

5. As summarized in the Examples and Figures of the present disclosure, the addition of acidic components of a hard candy at the beginning of the manufacturing process, including the cooking stage, results in a hard candy having a greater transmission than a hard candy produced by a process wherein the acidic components are added during the cooling stage that follows cooking. More specifically, Figure 3 and Table 1 of the present specification illustrate the surprisingly high transmission that is achieved when the acidic components of Example 1 was added during the cooking stage, as opposed to the process of Example 2 wherein the acidic components are added during a subsequent cooling stage. Therefore, although Examples 1 and 2 comprise hard candies having similar ingredients, a surprisingly high transmission is achieved by the addition of the acidic components of a hard candy at the beginning of the manufacturing process.

6. *Rivier I* fails to disclose or suggest a glassy amorphous solid having an improved transparency as evidenced by a transmission of at least 47.8% at 450 nm; and/or at least 50.9% at 550 nm; and/or at least 52.3% at 650 nm. In fact, at no place in the disclosure does *Rivier I* even recognize any glassy amorphous solid having a specific transmission, let alone the improved transmission of the glassy amorphous solid as described herein above.

7. *Rivier I* teaches a conventional process for producing confectionery products wherein acidic components are added after cooking. Specifically, *Rivier I* teaches a casing whose recipe is composed by 80% isomalt, 10% maltitol syrup and 10% water that is cooked to



high final solids until 145°C. The mass is then put in batch under a slight vacuum (0.9 atm.) for 3 minutes. The cooked mass is then discharged on a cooled table and 1% citric acid, 0.15% lemon flavour, 0.8% Acesulfame K are added. The ingredients are mixed until a plastic mass is formed. This mass at 75°C is then introduced in the batch roller. This process will not result in a glassy amorphous solid having an improved transparency as evidenced by a transmission of at least 47.8% at 450 nm; and/or at least 50.9% at 550 nm; and/or at least 52.3% at 650 nm. In fact, because *Rivier I* teaches a conventional process for producing confectionery products wherein acidic components are added after cooking, the resulting transmission will be less than the presently claimed transmission of at least 47.8% at 450 nm; and/or at least 50.9% at 550 nm; and/or at least 52.3% at 650 nm. Because *Rivier I* teaches that the acidic components are added after cooking and because *Rivier I* does not disclose improved transmission properties, *Rivier I* cannot teach the improved transmission properties of the confectionery product discussed herein above or disclosed in the present application.

8. *Rivier II* fails to disclose or suggest a glassy amorphous solid having an improved transparency as evidenced by a transmission of at least 47.8% at 450 nm; and/or at least 50.9% at 550 nm; and/or at least 52.3% at 650 nm. In fact, at no place in the disclosure does *Rivier II* even recognize any glassy amorphous solid having a specific transmission, let alone the improved transmission of the glassy amorphous solid as described herein above.

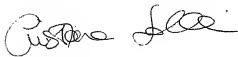
\* 9. *Rivier II* teaches a conventional process for producing confectionery products wherein acidic components are added after cooking. Specifically, *Rivier II* teaches that a mixture of 80 Kg of isomalt F, 10 Kg of maltitol syrup and 10 Kg of water is cooked under 60% vacuum until reaching a cooking temperature of 155°C. Subsequently, the resulting cooked mass is flavoured, coloured and acidified and cooled down at 70°C. This process will not result in a glassy amorphous solid having an improved transparency as evidenced by a transmission of at least 47.8% at 450 nm; and/or at least 50.9% at 550 nm; and/or at least 52.3% at 650 nm. In fact, because *Rivier II* teaches a conventional process for producing confectionery products wherein acidic components are added after cooking, the resulting transmission will be less than the presently claimed transmission of at least 47.8% at 450 nm; and/or at least 50.9% at 550 nm;

and/or at least 52.3% at 650 nm. Because *Rivier II* teaches that the acidic component is added after cooking and because *Rivier II* does not disclose improved transmission properties, *Rivier II* cannot teach the improved transmission properties of the confectionery product discussed herein above or disclosed in the present application.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 12/06/2007

Print Name Cristiana Soldani



\_\_\_\_\_

**RELATED PROCEEDINGS APPENDIX**

None.